

IMPLEMENTATION OF A PHARMACIST/PHYSICIAN-INITIATED  
VOLUNTARY PROGRAM TO CURB AMPHETAMINE AND METHAQUALONE ABUSE

By

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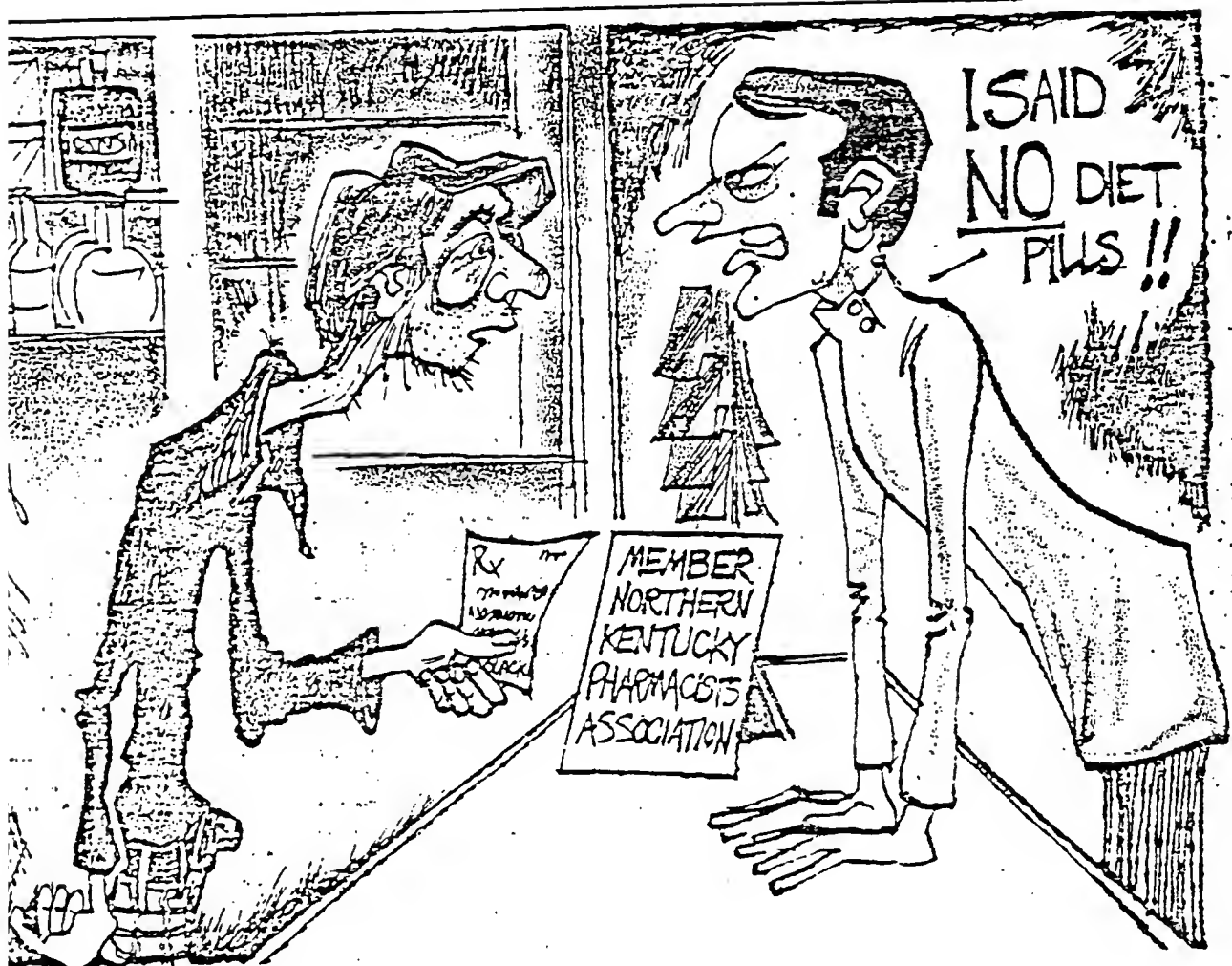
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The Pharmacists' Praiseworthy Initiative  
Cincinnati Enquirer, October 24, 1976 [1]

To my wife, Debe

This work of art is dedicated to you,  
for your help and patience and all you do.  
These words of wisdom from Kibran I must say  
for they mean as much now as in his day.

"For even as love crowns you so shall he  
crucify you. Even as he is for your growth  
so is he for your pruning.

Even as he ascends to your height and  
caresses your tenderest branches that  
quiver in the sun,

So shall he descend to your roots and  
shake them in their clinging to the earth."

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By

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Major Department: Pharmacy

In 1976, local attention was drawn to the high per capita consumption of amphetamines and methaqualone in the Jacksonville, Florida, area. To help alleviate the problem, the Duval County Pharmacy Association, Medical Society, and Osteopathic Society designed a voluntary program aimed at discouraging unnecessary prescriptions for these drugs, reducing forged prescriptions, and deterring pharmacy robberies.

The plan was to remove methaqualone and amphetamine products from pharmacy inventories by establishing a 48-hour time delay in the dispensing of prescriptions for these drugs and to allow pharmacists time to verify prescriptions with physicians and to order the drugs from the wholesalers.

There were three phases to this evaluation of the Duval County program. First, all Schedule II prescriptions for one year preceding and two years following initiation of the program were audited in random samples of thirty Duval County pharmacies and ten Alachua County pharmacies. Second, pharmacists in each of the thirty Duval County pharmacies and 396 Duval County

physicians practicing in the county during the entire time encompassed by the study were surveyed to determine their opinions and knowledge concerning the program. And third, the implementation process by which the voluntary program was executed was assessed for effectiveness and timeliness.

In the thirty Duval County pharmacies, amphetamine prescriptions decreased over 80 percent in the two years after program implementation while methaqualone prescriptions were reduced more than 55 percent. A positive spillover effect resulted in a 57 percent decrease in the prescription volume of phenmetrazine since a majority of the practitioners erroneously believed that it was also included in the program.

The survey results indicated that pharmacists and physicians thought that the program had succeeded in accomplishing its goals and that it was, in general, a good concept. The implementation assessment revealed a weakness in the information dissemination process.

The Duval County program provided an excellent model for the implementation of similar programs. The program exhibited the highest degree of peer review. More joint programs of a like nature are needed in order to help solve the problem of drug abuse and drug misuse in our society.

## CHAPTER I

### INTRODUCTION

In 1977, the Duval County Pharmacy Association, the Duval County Medical Society, and the Duval County Osteopathic Society, in response to the serious problem of methaqualone and amphetamine misuse in Jacksonville, Florida, collaborated in an uncommon showing of interprofessional cooperation and designed a program to alleviate the problem. The basis for this program was a belief that excessive quantities of amphetamine and methaqualone were being obtained pursuant, mostly, to legitimate prescriptions, and possibly, to a lesser extent, pursuant to forged prescriptions.

The joint program, which was wholly voluntary in nature, entailed

- (1) a publicity campaign directed at the public, physicians and pharmacists to familiarize them with the problem. This was accomplished via the printed media and discussions at professional meetings;
- (2) the establishment of a 48-hour waiting period in the dispensing of prescribed amphetamine and methaqualone to provide adequate time for pharmacists to verify the prescription's validity with the prescriber and to order the drug product from the wholesaler; and
- (3) prescribing of these drugs in stock-size container quantities to prevent retention of partial packages in inventory.

It was anticipated that these activities would curb inappropriate prescribing, aid in the detection of forgeries and aid in the prevention of drug related robberies.

In conducting a proper evaluation of the implementation and outcomes of the "Duval County program" to combat a portion of the overall problem of drug abuse, it was essential to study the historical development of drug abuse control and why it was necessary for these health professionals to pioneer this type of voluntary drug control.

This chapter is divided into two sections: (1) a historical perspective on drug control, and (2) a description of the purpose and the objectives of this evaluation of the Duval County program.

### A History of Controlled Drug Regulation (1906-1982)

#### Control of Narcotics

Drug abuse is a problem that has plagued mankind for many centuries [2]. Modern attempts to control this problem began with the enactment of the Harrison Narcotic Act, [3] which went into effect on March 1, 1915. The Harrison Act controlled the distribution of "narcotic substances"<sup>1</sup> through the federal government's power to levy taxes. The administration of the law was under the control of the then Internal Revenue Department. Narcotic drugs could be purchased only pursuant to a special order form and be dispensed by the pharmacist only upon receipt of a practitioner's written order. The law placed tight controls on all narcotics, but had less stringent controls on those narcotics with a lesser degree of addiction potential. Narcotic preparations

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<sup>1</sup>"Narcotic substances" means cocoa leaves and opium and every substance neither chemically nor physically distinguishable from them [4].

in legitimate commerce under the Harrison Narcotic Act, as amended, were eventually categorized accordingly:

Class A - These narcotics could be dispensed only pursuant to a practitioner's written order and were non-refillable.

This class included most single ingredient narcotic preparations, e.g., opium, cocaine, and morphine;

Class B - Originally, these narcotics could be dispensed only pursuant to a practitioner's written order, but the law was later changed to permit oral orders. These were originally non-refillable. This class contained most combination narcotic preparations, e.g., aspirin compound with codeine and hydrocodone syrup;

Class X - These were the "exempt narcotics" that could be obtained in limited quantities by the patient upon signing the narcotic register. These preparations included Elixir Terpin Hydrate and Codeine (ETH and C) and paregoric; and

Class M - These narcotics were those opiate derivatives that showed no addiction potential but were controlled because of their natural origin from *Papaver Somniferum* (Opium Poppy). These preparations included paperverine and noscapine.

#### Control of Stimulants and Depressants

Stimulants and depressants were not regulated by the Harrison Act because they were not classified as "narcotic drugs" and were subject only to the requirements of the Pure Food and Drug Act of 1906 [5].

Amphetamines were first synthesized in the early twentieth century. Methamphetamine was first prepared by Ortega, Inc., in 1919 [6:78]. Benzedrine<sup>®</sup> (Amphetamine Sulfate) was synthesized by a California pharmacist, Gordan Alles, in 1927 [7:183]. These were the first of the amphetamines to be manufactured. The first amphetamine to be marketed was Benzedrine<sup>®</sup> in 1932. It was introduced in an inhaler dosage form for nasal decongestion and attained immediate wide-spread use [7:11]. It was not until 1936 that the first misuse of amphetamines was reported in the United States at the University of Minnesota among many of the students studying for finals [6:96]. In 1938, amphetamines, along with many other drugs, became subject to the provisions of the new Federal Food, Drug, and Cosmetic Act (FD & C) [8].

The epidemic misuse of amphetamines was first reported among German paratroopers in the Spanish Civil War, in 1939 [6:96], and later among American soldiers in the 1940's [6:97] and again in post-World War II Japan [6:98]. By 1949, the Benzedrine<sup>®</sup> inhaler had to be removed from the market, because of extensive abuse [6:99]. The stimulants phenmetrazine (Preludin<sup>®</sup>) and methylphenidate (Ritalin<sup>®</sup>) were first marketed in this country in the early 1960's.

Methaqualone was first introduced as a somnifacient by M. L. Gujral in India in 1950 [6:99], but was not marketed in the United States until the early 1970's. It received wide acceptance and was marketed under many trade names including Quaalude<sup>®</sup>, Sopor<sup>®</sup>, Parest<sup>®</sup>, and Somnafac<sup>®</sup>.

During the mid-sixties, the public generally became aware of the abuse of many non-narcotic substances. "Uppers," "Bennies," "Dexies," "pep pills," "downers," "dolls" and "yellow jackets" became household words. In view of the growing recognition of wide-spread abuse of



stimulants and depressants, in addition to narcotics, Congress enacted the Drug Abuse Control Amendments [9] (DACA) to the FD & C Act in 1965.

It was the first attempt by the federal government to control stimulant and depressant drug abuse. The act was administered by the Food and Drug Administration (FDA) Bureau of Drug Abuse Control (BDAC) [9]. All amphetamine-containing products and phenmetrazine were regulated. The act required that an inventory of all regulated stimulants and depressants be taken by pharmacists, manufacturers and wholesalers on February 1, 1966. Thereafter, records had to be maintained for the receipt and disposition of all regulated drugs.

#### Consolidated Federal Control

In 1968, BDAC was transferred from FDA to the Department of Justice's Bureau of Narcotics and Dangerous Drugs (BNDD) when federal drug enforcement operations were consolidated [10]. BNDD was succeeded in 1973 by the Drug Enforcement Administration (DEA).

Increased public attention and federal regulation did not eliminate amphetamines as a major drug of abuse. The continued recreational use of amphetamines and other drugs by the "hippy movement" in the late 1960's was only one of the many examples of the failure of federal legislation [11]. "Despite repeated raisings of the regulatory ante, FDA felt that too many Americans were taking too many 'uppers' for too many of the wrong reasons." [11]

On October 27, 1970, President Nixon signed into law the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 [12]. There are three pertinent sections to the law: Title I establishes rehabilitative programs for drug abusers; Title II, commonly referred to as the

Federal Controlled Substance Act (CSA), is the mainstay of drug control; and Title III, regulates the importation and exportation of "Controlled Substances." This Act superseded all of the more than 50 laws that regulated narcotics and other dangerous drugs.

The CSA essentially establishes control through registration of all persons in the "legitimate chain of procurement," except the ultimate consumer. Congress exacted its authority to enact the CSA from Article 1, Section 8 of the United States Constitution, the power to regulate interstate commerce, rather than from its power to levy taxes, which it had previously used in controlling narcotics.

The CSA effectively consolidated all federal control over narcotic, stimulant and depressant drugs in one agency. The BNDD was retained as the controlling agency. The act differentiated between drugs according to their potential for abuse and they were categorized accordingly:

Schedule I - These drugs have a very high potential for abuse and  
C-I have no currently accepted medical use in the United States. They may not be prescribed but they may be used for research purposes under strict guidelines. Examples of drugs included in this class are heroin and marijuana;

Schedule II - These drugs have a very high potential for abuse and  
C-II have a currently accepted medical use in the United States. They may be dispensed only pursuant to a registered practitioner's written order and no refills are permitted. Examples of drugs included in this class are opium, cocaine and morphine;

Schedule III - These drugs have a lower potential for abuse than do C-III C-I or C-II drugs. Oral orders are permitted and not more than five refills over a six-month period are permitted, if authorized by the practitioner. Examples of drugs included in this class are glutethimide, aspirin compound with codeine and methyprylon;

Schedule IV - These drugs have a lower potential for abuse than C-IV C-III drugs. Examples of drugs included in this class are meprobamate and chloral hydrate; and

Schedule V - These drugs have a lower potential for abuse than C-V C-IV drugs. Refills are limited only by the prescribing practitioner. Examples of drugs included in this class are ETH & C and acetaminophen with codeine elixir.

Amphetamines, originally categorized in Schedule III, were subsequently placed in Schedule II in order to further restrict their availability [13]. Methylphenidate and phenmetrazine, also originally categorized as Schedule III drugs, were later placed in Schedule II in late 1971 [14].

Methaqualone was not a controlled substance when it was first marketed. However, in early 1973, pressure began to mount in Washington for its control. After a scathing exposé about the high abuse rates and addictive potential of methaqualone, on "60-Minutes," The CBS news magazine television show, the federal government moved quickly to control the drug. After much debate, it was placed in Schedule II [15].

### Regulatory Control

The DEA and FDA have attempted, by promulgating regulations, to further limit the supplies of dangerous stimulants. The first effort resulted in a regulation which established manufacturing production quotas for amphetamines [16]. In 1970, the industry produced a sufficient quantity of bulk amphetamines and methamphetamines to manufacture 1.5 billion 10 mg tablets (15,000,000 grams). This was the first year for the quotas. The 1971 quotas were 5,870 kilograms of amphetamine and 2,782 kilograms of methamphetamines (8,652,000 grams) [17], a sharp reduction from the 1970 quotas. Aggregate quotas are established for the entire industry. They are based on the agency's estimate of "legitimate medical needs."

In response to reports from the National Institute of Mental Health (NIMH) [18] and lobbying by public pressure groups, the 1972 quotas were set at 17.7 percent of the 1971 production and were only 8.8 percent of the manufacturers' 1972 requests [19, 20]. The 1972 quota was 1,564 kilograms of amphetamines and 969 kilograms of methamphetamines (2,533,000 grams) [20]. As the figures above indicate, the quota system alone was responsible for reducing the availability of legitimately manufactured amphetamines by over 80 percent.

The second effort to limit the supply of amphetamines was the FDA's attempt to remove amphetamine-combination products from the market via an "amphetamine class action" recall based on the DESI review<sup>2</sup> recommendation

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<sup>2</sup>Drug Efficacy Study Implementation (DESI) review was the process that the FDA followed to comply with the 1962 Kefauver-Harris amendments to the FD & C Act. FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to review for efficacy all drugs marketed between 1938 and 1962.

that these drugs were "less than effective" for their indicated uses [21]. The FDA moved to remove parenteral amphetamines and amphetamine-combination products from the market on March 30, 1973 [22] by issuing an immediate ban on their further distribution. Several large manufacturers<sup>3</sup> filed suit to stop implementation of the ban. A stay was granted. There was another "on-again-off-again" battle before FDA finally lost [23, 24]. Nevertheless, Smith, Kline and French (SKF), the largest manufacturer of these products, eventually removed its Dexamyl<sup>®</sup> and Eskatrol<sup>®</sup> from the market because of disproportionate legal costs.<sup>4</sup> [25, 26]

The third effort by the FDA was its attempt to remove the weight reduction indication from product labeling [27, 28]. This indication accounted for 88 percent of amphetamine usage in 1976 [29]. However, after more than eleven years of effort, FDA has been able to require only that the labeling regarding the period of effectiveness for these drugs' anti-obesity indication be limited to two weeks [30].

A fourth effort, by the DEA and the FDA, to limit the availability of stimulants, was the scheduling as controlled substances of non-amphetamine anorectics that are legend drugs. The rationale in this instance was to limit their potential for use as replacements for amphetamines [11].

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<sup>3</sup>The manufacturers involved in this law suit were: Smith, Kline and French (Dexamyl<sup>®</sup>, Eskatrol<sup>®</sup>), Lederle (Bamadex<sup>®</sup>), Obetrol (Obetrol-10<sup>®</sup> and -20<sup>®</sup>), and Delco Chemical (Delcobese<sup>®</sup>).

<sup>4</sup>Joseph L. Rutledge, Vice President for Customer Affairs for SKF, stated in a letter to pharmacists, "it became apparent that lengthy and costly administrative and judicial proceedings lay ahead, and a great deal of time and resources would be required to continue the controversy ....the decision was made to terminate the controversy and to discontinue distribution of this product."

Federal attempts have reduced the annual number of prescriptions for amphetamines to 25 percent of their annual average in the 1960's decade [2]. Nevertheless, drug abuse remained a substantial problem according to the latest reports from FDA [2] and National Institute of Drug Abuse (NIDA) [31]. Of all categories of prescription drugs, stimulants represent the therapeutic category most frequently abused [2]. NIDA states that the non-medical use of stimulants is rapidly increasing in the 18- to 25-year-old group. Amphetamines have rates of abuse ten times those of other drugs relative to prescription sales [2].

Along with the "clamping down on 'uppers'" there has been a simultaneous "tightening up on 'downers'" [32]. The FDA is currently re-evaluating its position regarding Schedule II sedatives and hypnotics (methaqualone and certain barbiturates). An FDA-sponsored committee is studying these drugs and their "use by the elderly, problems of chronic use, cumulative effects of toxicity, the effects of statutes and federal regulations on prescribing, and the possibilities of non-pharmacological treatment of anxiety and insomnia, the two indications for which these drugs are most often prescribed." [32]

### State and Local Control

State officials dissatisfied with the lack of success of federal efforts to curb amphetamine misuse have enacted legislation aimed at further restricting their availability. In late 1977, Wisconsin became the first state to prohibit the medical use of amphetamine for anorexia [33]. New Jersey [34], South Carolina [35], New York [36], Washington [37] and Florida [38] have followed Wisconsin's example and have placed restrictions on amphetamine prescribing for weight reduction.

Two separate and different approaches in limiting amphetamine usage have been taken by Arkansas and Maryland. Maryland has restricted the quantity of amphetamine products that may be legally dispensed [39]. In Arkansas, before an amphetamine prescription is considered valid, a second physician's confirming signature is required [40].

The drug misuse problem has been attacked at the local level also. Several local professional associations have attempted to curb amphetamine misuse through voluntary means. The first of these efforts, undertaken in Huntington, New York, in 1971, called for the verification of the prescription by the pharmacist before dispensing [41]. Other actions taken include calling for a 48-hour "cooling-off" period before dispensing an amphetamine and restricting dispensing of amphetamines to stock-size packaging [42, 43]. One such voluntary program is the subject of this study and is detailed in the next section.

#### The Duval County Voluntary Program

In 1976, Jacksonville, Florida, had one of the highest per capita consumptions of amphetamines in the country.<sup>5</sup> Cy Kothman, then president of the Duval County Pharmacy Association, presented evidence to the city's health department, local medical societies, and the local press that six Jacksonville physicians were responsible for 90 percent of all amphetamine and methaqualone prescriptions in the area [44, 45].

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<sup>5</sup> Although the basis, in fact, for this statement is elusive, it was an important component of the overall effort by Cy Kothman to elicit the support of the Duval County Medical Society, County Health Department, the Duval County Pharmacy Association and The Jacksonville Journal. Because all of them believed this to be a fact, it was included here. This indictment was made in an article appearing in The Jacksonville Journal on May 12, 1977.

By late 1977, the Duval County Pharmacy Association (DCPA), the Duval County Medical Society (DCMS) and the Duval County Osteopathic Society, had announced "plans to voluntarily remove amphetamines and methaqualones from the shelves of local pharmacies" [46]. The position of the DCMS, according to its president, Guy Selander, M.D., was that the physicians wanted to be part of the solution, not part of the problem by "seeking to reduce the amount of 'legally secured' drugs trafficked in Jacksonville" [42, 46]. The program began on December 2, 1977 [42, 47] as a totally voluntary cooperative attempt at self-regulation.

The Duval County program was modeled after a 1976 Kentucky program in which the northern Kentucky Pharmacists' Association and three county medical societies joined together to limit amphetamine distribution [48]. The Kentucky plan was divided into four parts. First, all amphetamine products were removed from pharmacy inventories. Second, the physicians would indicate the diagnosis on all prescriptions for amphetamines. Third, prescriptions would be written only for stock-size packages. And, fourth, the physician would advise the patient that the pharmacist must order the medication and there would be a delay before the prescription could be filled [48].

Differing slightly, the Duval County plan was divided into three parts. First, there was the removal of methaqualone and amphetamine drugs from pharmacy inventories. Second, there was to be a 48-hour waiting period in filling these prescriptions. This was to allow the pharmacist time to verify the prescription's validity and to order the drug from a local wholesaler. The delay would discourage forgeries and prescriptions from "fat clinics" and "prescription-mill" physicians. And, third, the prescriptions were to be written only for stock-size packages in order



to prevent the retention of partial packages in the pharmacy as a deterrent to robberies and burglaries [49].

The Duval County program had several important aspects, the most heartening of which was the pioneering of voluntary drug control by pharmacists and physicians. This cooperative effort by health care professionals to establish a voluntary compliance program would portend well for the future control of drug abuse, if successful. Also heartening was the enthusiastic cooperation of the local press in eliciting public support. Twelve feature articles in The Jacksonville Journal and The Florida-Times Union supporting the program were written in the six months prior to the program's inception.

This collaboration of health care professionals to help solve part of the problem of drug abuse attracted the interest of other Florida pharmacists, DEA administrators and state legislators. Four other Florida counties, Broward, Dade, Hillsborough and Orange, subsequently initiated programs incorporating many of the features of the Duval County experiment [50].

#### The Florida Amphetamine Law

Despite the fact that the national press was attributing great apparent success to the Duval County program [1, 45, 51, 52], the Florida Legislature decided to mandate amphetamine prescription reduction. In late 1979, the Florida Legislature proposed severely restrictive drug control legislation with many elements similar in nature to the Duval County program [53]. A compromise bill which limited practitioners' prescriptive rights was enacted amending the Medical, Osteopathic and Dental Practice Acts [54] making it improper medical practice to prescribe,

dispense, sell, administer, or supply amphetamines or any Schedule II sympathomimetic amines (e.g., phenmetrazine) for weight-control [55]. This law became effective October 1, 1980.

Figure 1 shows the time-frame relationship of the Duval County program and the Florida Amphetamine Law. As can be seen from the figure, this law superseded the Duval experiment.

### The Study

As this review indicates, Florida has already chosen a different method for restricting amphetamine availability, but national attention continues to be focused on the problems of drug abuse, especially the use of stimulant and depressant drugs. With the solutions to a continuing problem through public policy unclear, there is an even greater need to look at innovative programs in order to provide information on their implementation, usefulness and effectiveness for consideration in future policy efforts.

### The Significance of This Project

Recently, the Florida Legislature has proposed legislation modeled after the Duval County plan for methaqualone [56] and for all other non-emergency Schedule II prescriptions [57]. Before legislation is enacted which incorporates the salient features of the Duval County program, a careful assessment should be made to evaluate the effectiveness and the strengths and weaknesses of the program. The questions needing answers include:

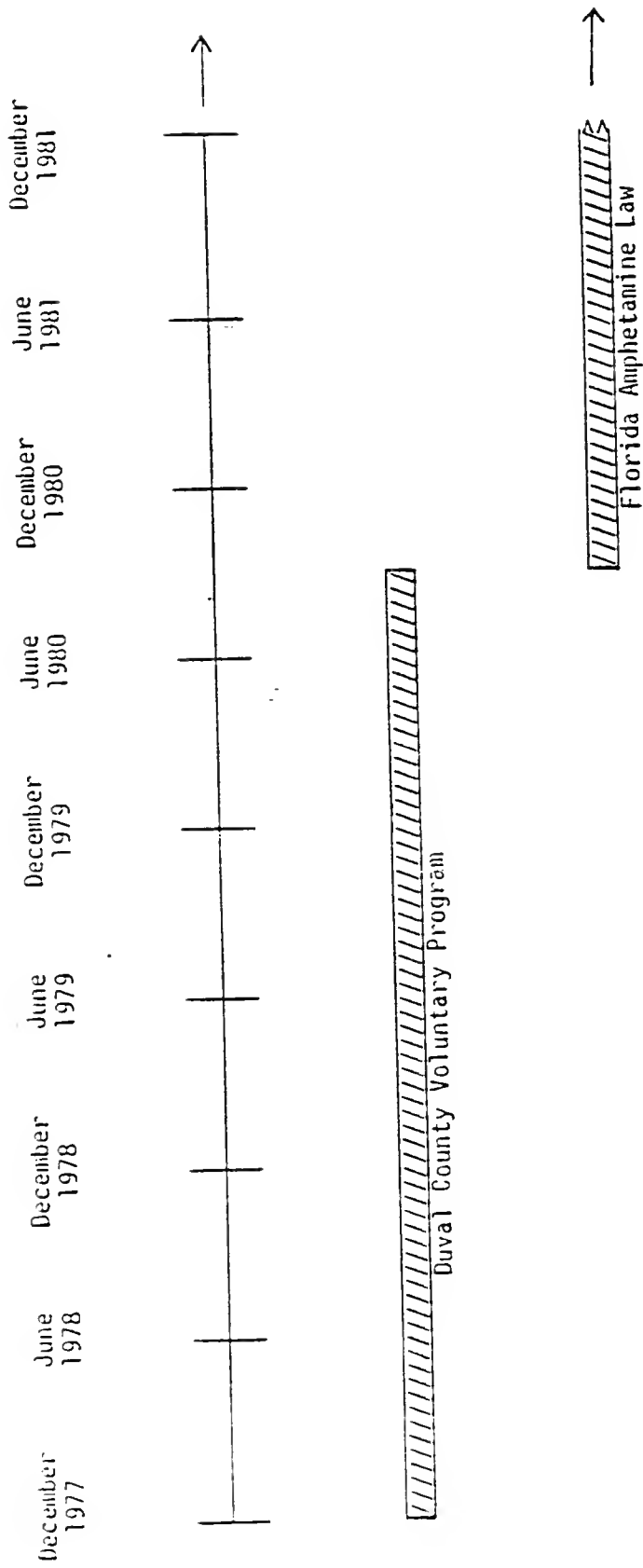


Figure 1. Time-Frame Relationship of Duval County Program and Florida Amphetamine Law

- (1) Was the Duval County program successful in decreasing the number of prescriptions for amphetamines and methaqualones?
- (2) If there was a decrease, what was the actual percentage?
- (3) What actions did pharmacists and physicians take in initiating the program?; and
- (4) What are the attitudes of pharmacists and physicians (the health professionals upon whom the success of such a program relies) to this and other types of drug abuse control?

These four questions can be focused into two areas of primary concern: first, the evaluation of the voluntary program's outcome and second, the examination of the participants' attitudes and actions in implementing the goals of the program. These foci will guide this evaluation of the Duval County program.

#### Research Objectives

In seeking answers to the concerns outlined above, the researchable objectives for the study of the Duval County program, divided by foci, can be stated as follows:

- A. First, evaluation of the program's outcome,
  - (1) to identify changes in the prescribing and dispensing behaviors for amphetamines, methaqualone, phenmetrazine, and methylphenidate in Duval County during the period beginning one year prior to the program's initiation and ending two years after its inception; and
  - (2) to determine the degree of participation by Duval County pharmacies.

Accomplishment of these objectives will provide documentation on whether the program succeeded in accomplishing its primary goals. The dependent variables for the first objective will be amphetamine or methaqualone prescriptions as a percentage of all Schedule II prescriptions. These ratios by pharmacy and county will indicate any decrease in the level of prescriptions for these two drugs. The dependent variable for the second objective will be the participatory percentage of pharmacies. These results will be compared to an expected level of participation for similar programs, either voluntary or mandatory. This participation norm will be derived from the literature.

These two objectives are the mainstay of this study. In order to accomplish an evaluation of the implementation of any voluntary program it is necessary to evaluate the coverage level (degree of participation) and the outcomes (successfulness of program in fulfilling its goals) of the program. These evaluations are necessary, but to achieve a more comprehensive evaluation of the program, additional foci are required.

- B. Second, examination of the participants' attitudes,
  - (1) to examine the pharmacists' attitudes toward the Duval County program; and
  - (2) to examine the physicians' attitudes toward the Duval County program.

Accomplishing these latter objectives will sufficiently aid the interpretation of the former objectives, to provide a comprehensive evaluation. The dependent variables for these objectives are Accuracy Rating (respondents' score on the knowledge questions) and Precision (respondents' ability to differentiate specifics of the program). These

scores will provide a measurement of the participants' knowledge of the various facets of the program.

The next chapter addresses the policy implementation literature and its applicability to the Duval County program.

## CHAPTER II

### POLICY IMPLEMENTATION LITERATURE REVIEW

When the Duval County program was being formulated, the Duval County Pharmacy Association, the Duval County Medical Society, and the Duval County Osteopathic Society, by designing a program intended to alleviate the problem of amphetamine and methaqualone misuse in Jacksonville, were making policy. The voluntary program which they instituted was the result of joint policy decisions by members of each association. Implicit in the adoption of the decision was the anticipation that the program would achieve its goals. The primary goal of the program was to bring about a reduction in the number of legitimately prescribed amphetamine and methaqualone prescriptions. If this goal could be attained, then a substantial decrease in the availability of the two drugs "on the street" might be expected [46]. Two secondary goals of the program were, one, to effect a decrease in the incidence of forged prescriptions for these drugs [47] and two, to effect a reduction in the incidence of drug-related robberies [46].

Local policies, like federal and state policies, are rarely "self-executing." Congress may legislate drug abuse control measures [9], regulatory agencies may issue guidelines [58] or the President may order the rescue of United States hostages held in Iran - but in the absence of effective implementation plans, it is unlikely that decisions of policymakers will be carried out with much success [59:xii]. The vast majority of

policy implementations require a combination of positive actions by many people [60:10].

For the purposes of this study, implementation will have the following definition: "fulfilling an obligation; giving effect to; carrying out" [61:354]. Policy implementation will be considered as the stage between policy establishment - such as the formulation of the Duval County program - and the final outcomes on the people or organizations which it affects [62:1].

It is necessary that the outcomes of a policy decision be evaluated, but evaluation alone is not sufficient unless an understanding is reached as to why a particular outcome was achieved. "Information on implementation is critical for decision-making regarding future programs." [62:8]

There is a paucity of resource material available in the area of implementation literature [59:xiii]. Therefore, most of the citations are from one reference, Implementing Public Policy by George Edwards III. This chapter is divided into four sections, corresponding to the four critical factors in implementing public policy as detailed by Edwards [62:10]:

- (1) Communication;
- (2) Resources;
- (3) Attitudes; and
- (4) Organizational Structure.

#### Communication

In order to achieve effective implementation of a policy or program, the implementing personnel must have accurate knowledge of their expected activities since the people who make the decisions are usually not the



ones who will implement it [63]. Faulty transmission of information or inaccurate perception of implementation orders by the implementers are but two of the obstacles that may hinder proper and effective implementation [62:17]. These potential obstacles highlight the necessity of having an awareness of several key points to be considered in the establishment of an efficient communication system for implementation activities. The key points are

- (1) transmittance of concise, direct orders;
- (2) transmittance of clear, but flexible directives; and
- (3) consistency of objectives with goals [62:40].

The first key point concerns the transmission of directives. Before a decision can be implemented, the implementing personnel must have knowledge both that the decision has been made and that the time is appropriate to begin implementation. There are several obstacles to efficient transmission of information. First and foremost, is the barrier that the implementers may not agree with their instructions [64]. This may result in distortion or subversion of the decision and goals or a total blockade of the implementation [62:18]. Second, the absence of direct, established channels of communication may also result in the distortion of instructions [65]. Third, progress toward program fulfillment may be hindered by the implementers' inability to accept the communications or the implementers' lack of knowledge and understanding of the programs' goals [66]. Therefore, as a first step to ensure proper implementation, decision-makers must transmit concise orders directly through established channels of communication and be aware of the implementers' attitudes toward the decision.

The second key point relates to the clarity of the instructions. Vague orders provide implementers with the latitude to attach meanings to

policies different from those which were intended [62:26]. There are several factors which may lead to a lack of clarity of directives. Among these are complexity of the issue [62:26]; potential alienation of interest groups [67:265]; consensus and priority-setting of competing goals [60:9]; and, accountability avoidance by implementers or decision-makers [68:265]. While it may be desirable to strive for a high degree of clarity in the directives, overspecificity may reduce the degree of adaptability necessary for tailoring a policy to meet changing situations [62:34]. A "disciplined flexibility" is needed to prevent red-tape bog-down and to avoid rigid commitment to meeting the "letter of the law" rather than the "spirit of the program." [69:82]

The last key point involves the consistency of the communications. Contradictory directives are not only inefficient but also provide implementers with opportunities to exercise their own interpretations of the policy goals. "When implementers receive inconsistent instructions, they will inevitable be unable to meet all the demands made upon them." [62:45]

Accurate, concise, clear and consistent directives must be transmitted to the implementers in a direct and timely manner. This can best be accomplished by eliminating complexity, and by maintaining a small, cohesive group responsible for implementation [62:43]. Substantial planning and knowledge of the implementers' attitude is necessary for the establishment of a communications base. Direct and established communication links to the implementers are required to make the communication base both an effective and an efficient channel for beginning the implementation process. Inappropriate communications may mean that directives will not be

efficiently executed or that implementers will have the discretion to execute them in a manner contrary to what was intended [62:43].

### Resources

The second step in ensuring proper implementation of a policy is the provision of resources adequate to perform the required tasks. Adequacy of resources encompasses not only money, but also sufficient staff with necessary skills, timely access to pertinent information, authority commensurate with responsibility, and adequate facilities and supplies [59:xii]. Without the wherewithal to execute implementation directives, the process most likely will be ineffective, even though the orders might have been transmitted clearly and concisely.

The most fundamental resource is an adequately-sized staff which possesses the necessary skills. Staff-size inadequacy is the principal reason for implementation failures [62:54]. This type of personnel shortage exists in every level of government, therefore, the delegation of implementation activities to other governmental levels rarely results in an increase in efficiency [70]. Two consequences of inadequate staffing are; one, a high degree of ineffectiveness in executing directives, and two, limitations in regulating or monitoring implementation activities [62:79].

The second fundamental resource is information. Two types of information are necessary for efficient implementation [69:114]. The first type of information provides knowledge of how to execute a policy. The second type is obtained from data generated from monitoring the compliance of organizations or individuals affected by the guidelines of the policy. The latter type of information is often very difficult to procure, usually due to an insufficient number of staff [62:80].

Another resource that may be essential for implementation is authority [71:276]. Implementers must be delegated sufficient authority to execute their directives. It is not always necessary nor always desirable to exercise such authority to its fullest extent. "One of the motivations behind such an approach is the obvious one of obtaining the cooperation of others through the creation of goodwill." [62:81]

The last important resource is physical facilities [62:77]. Facilities include buildings, supplies and equipment. A deficiency in any of these may impede efficient implementation [62:77].

Decision-makers must furnish those who will implement their policies with necessary and sufficient resources. These resources include an adequate staff with proper skills, pertinent and timely information as to the manner of implementing decisions and monitoring compliance, sufficient authority to make certain that directives are executed as originally intended, and enough facilities, supplies and equipment to efficiently implement policies. Inadequacy of resources may mean that directives from decision-makers will not be properly executed.

### Attitudes

The third step in ensuring effective implementation of a policy is understanding how the attitudes of implementers toward a particular policy affects their execution of directives concerning that policy [71:270]. A positive or neutral disposition towards a policy by the implementers usually poses no barriers to effective implementation. But policies that conflict with the interests of the implementers or are opposed by them for other reasons may have many obstacles blocking their effective implementation. When this occurs, policy-makers can take corrective measures

by manipulating the implementers' attitudes, by bypassing the implementers or by limiting the implementers' discretion in executing directives.

The first option involves the use of incentives. Since people usually act in their own best interest, augmenting the benefits to enhance the implementers' chances for advancement may influence their actions [71:324]. The major disadvantage to this approach is the potential for goal displacement [62:112]. If a standard of accomplishment is developed, implementers may accentuate the element that is being measured without any regard to its effect on the advancement of the policy's purpose.

The second option, bypassing the implementer, can be accomplished in two ways. The first way is to replace the pervicacious personnel with more responsive ones. Although this tactic may work in the private sector, it is rarely possible in the government bureaucracy where practically every employee is protected under the civil service system [72:345]. One of the few methods available in the public sector for overcoming such obstacles is the transfer of the obstructive personnel elsewhere, but this will merely shift the problem and not solve it. The second way involves the utilization of different personnel to implement the policies. This method is seldom viable as it would entail the creation of a new department [73:105].

The third option is to limit the implementers' discretion in executing directives. The problem is that this option is not always possible or even desirable. Because decision-makers have little authority over career bureaucrats in the government, it is not always possible to limit their discretion [69:186]. Neither is it always desirable [72:345]. The disadvantage of too-rigid guidelines is that they often restrict adaptation to changing environmental circumstances [62:34].

Decision-makers must be aware of the attitudes of the implementers toward the policy to be executed. "If implementation is to proceed effectively, not only must implementers know what to do and have the capacity to do it, but they must also desire to carry out a policy." [62:11] Failure to consider this critical factor may mean that such obstacles will effectively restrict efficient implementation, either directly through implementers' actions in not faithfully executing directives with which they disagree or indirectly through selective perception of communications.

### Organizational Structure

The final step to ensure effective implementation of a policy is to understand the impact of the organization's structure on the execution of directives. Two different aspects of structure, operational procedures and responsibility fragmentation, directly impact on the implementation process. The first aspect, standard operating procedures (SOPs) assists organizations in conserving time and resources for routine matters [71:133]. They are usually developed to compensate for a lack of resources. Ideally, they are used to simplify complex situations and to allow for the interchange of personnel. Although SOPs can achieve these positive accomplishments, they also can function as obstacles to the implementation of new programs because they are designed for routine circumstances and not for unusual situations [74:129]. SOPs can impede the implementation of new programs, especially those that require different *modi operandi* from established procedures [69:322].

The second aspect of organizational structure that impacts on implementation is fragmentation of responsibility. This is best exemplified by the federal bureaucracy [62:134]. Fragmentation persists in the federal system because three powerful entities, Congress, federal agencies and

special interest groups, advocate and continue to support the present system. Congressional committees do not want to relinquish control over their programs; federal agencies, likewise, are possessive about their programs; and special interest groups do not want to lose control over agencies they have "captured" or lose their special access to the other two groups. Responsibilities may be so fragmented that implementation functions are not executed, or are poorly executed.

Decision-makers must understand the structure of the organization that is responsible for implementation. SOPs, although valuable tools for making routine decisions, may be inappropriate for the different circumstances posed by novel programs. Fragmentation of responsibility may result in directives from decision-makers falling in between the cracks of agencies and never being executed. Figure 2 humorously illustrates how simple tasks can be made complicated [75:18]. Effective implementation requires an understanding of the organizational structure. Without this understanding, the implementation responsibility can be lost through organizational fragmentation or SOPs.

### Factor Interaction

Goal setting or decision-making does not cease after the goals have been set or the decision has been made. The effectiveness of the implementation process for these policies or goals may determine the final outcome. After policy formulation, special attention must be paid to resource availability, organizational structure, and to outside political interests if effective implementation is to occur. The four critical factors discussed in this chapter not only directly impact on the implementation process but they also indirectly impact by interacting with each other. Figure 3 details this interaction. A decision-maker who

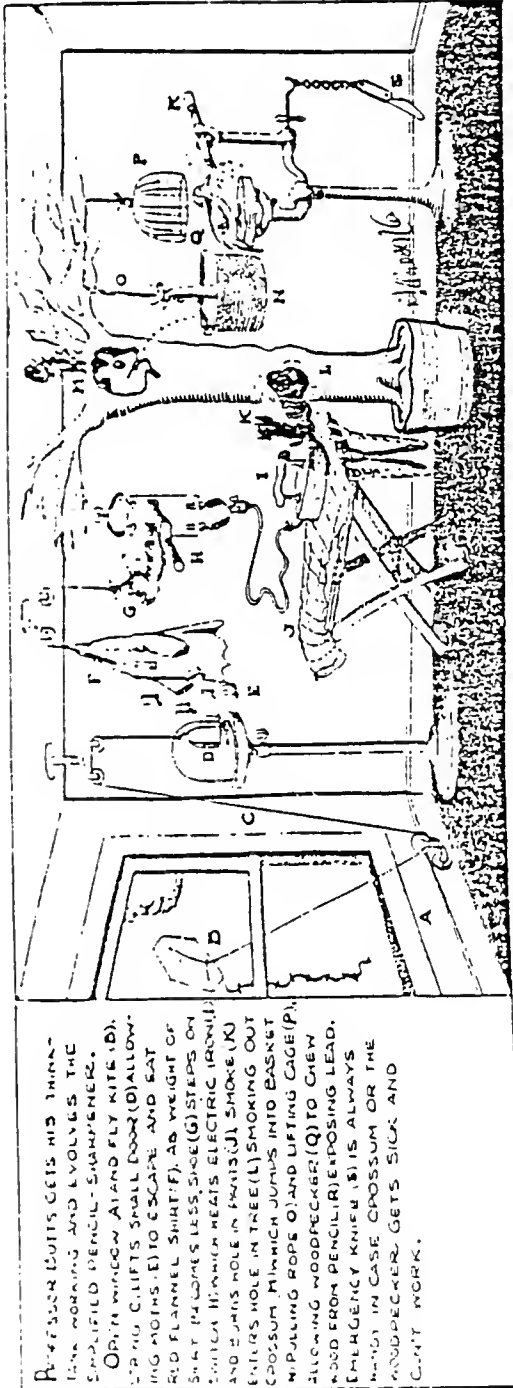


Figure 2. Does It Have to Be This Complicated? - A Comical Key [75:18]



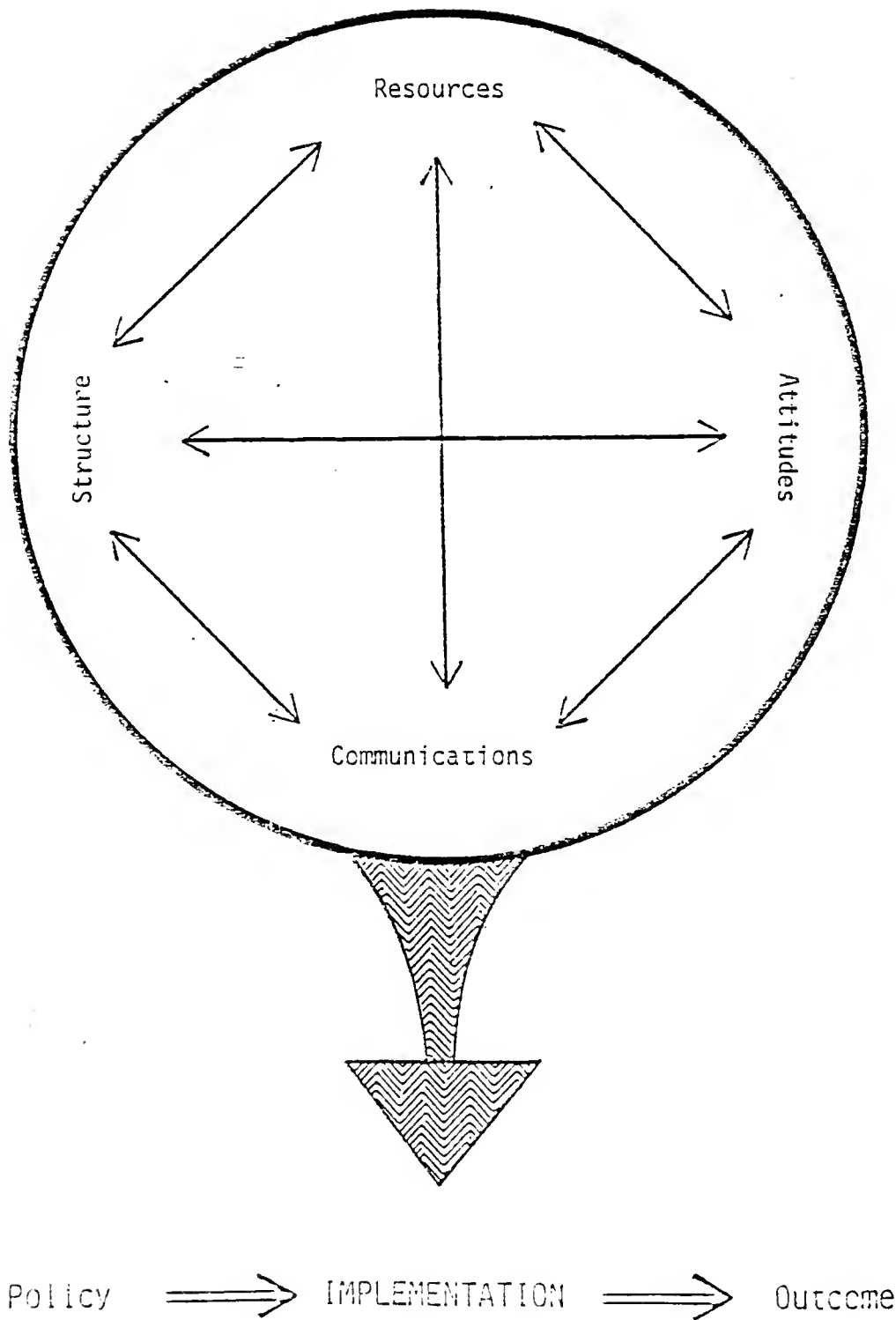


Figure 3. Interaction of the Four Critical Factors on the Implementation Process

desires to have his policies implemented in the most efficient manner must understand how these factors affect that process.

To summarize, there are four critical factors which impact on the implementation process. In order to have the most effective policy implementation, decision-makers must understand the roles which communications, implementer attitudes, resource scarcity, and organizational structure play and how to use this information to their advantage. These factors were examined in depth to provide the necessary background for understanding the impact of the implementation process on the final outcomes of a policy.

Future chapters detail the data collection methodology, the results obtained from the various data collection instruments, and the conclusions. The final chapter discusses the implementation process of the Duval County program and how it impacted on the final outcome of the voluntary program.

The next chapter addresses the methodology utilized for data collection in this study of the implementation of the Duval County program.

## CHAPTER III

### SURVEY, SAMPLING METHODS AND QUESTIONNAIRE DESIGN

This evaluation of the Duval County program was divided into four parts:

- (1) a telephone interview with a pharmacist in every Duval County community pharmacy in order to determine the degree of participation in the voluntary program;
- (2) a review of prescription records from a random sample of community pharmacies in the experimental (Duval) and control (Alachua) counties in order to identify changes in prescribing and dispensing behaviors for amphetamine, methaqualone, phenmetrazine, and methylphenidate;
- (3) a questionnaire completed by pharmacists in the sampled pharmacies in order to examine their attitudes toward the Duval County program; and
- (4) a questionnaire mailed to those practitioners in the study area categorized as potential amphetamine or methaqualone prescribers in order to examine their attitudes toward the Duval County program.

This chapter describes the procedures used in developing the data collection instruments and the procedures used in the selection of pharmacies, pharmacists and physicians. Also, sampling methods for the experimental and control groups are explained.

### Study Development

All of the data collection instruments used in this study were developed and pretested during the initial phase of this study. Both the pharmacists' and physicians' questionnaires were pretested on a portion of the population of Duval County pharmacists and physicians. The telephone interviews were begun in November 1980 and were concluded in January 1981. The pharmacy data collection pretest was started in January 1981 and was concluded in February 1981. The pharmacy data collection phase started in March 1981 and was completed in both the study and control counties by the middle of January 1982. The physician mail-questionnaire pretest began in August 1981 and finished in September 1981. The physician mail-questionnaire data collection phase began in September 1981 and was concluded in November 1981.

Figure 4 shows the time-frame relationship of the Duval County program, the Florida amphetamine law, the study period and the data collection period. As can be seen, the prescription review data is retrospective, therefore, these data were not influenced by the passage of the Florida amphetamine law. However, the pharmacists' and physicians' questionnaires were administered after the passage of the law, and therefore, may have been influenced by commentary about this and other laws which appeared in the media.

### Development and Pretest of Data Collection Instruments

Implementation of the study began with the design and development of questionnaires and prescription review techniques. The instruments were tested and evaluated with regard to the time required for completion, possible bias introduced by specific wording, and clarity of the meaning

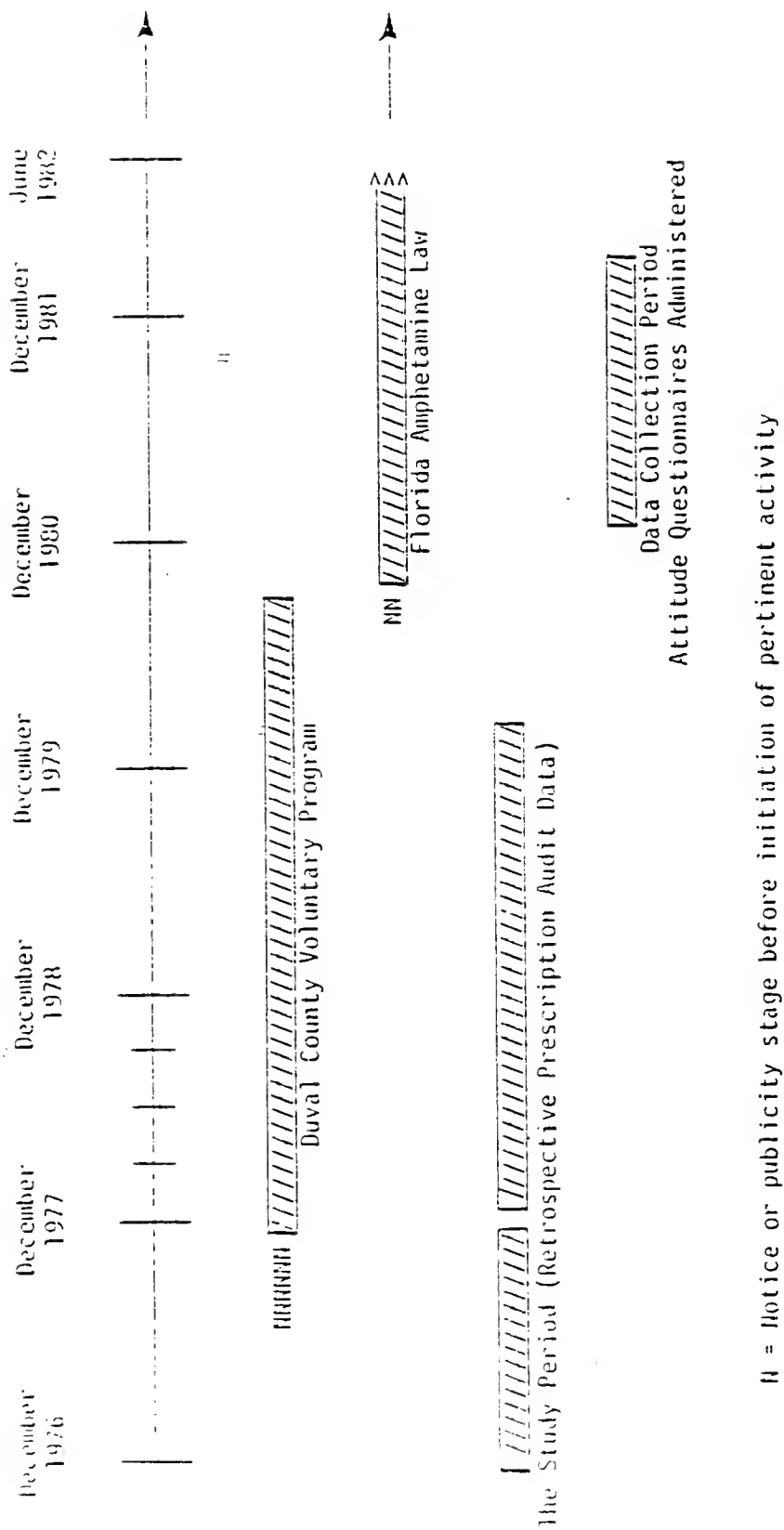


Figure 4. Time-Frame Relationship of Duval County Program, Florida Amphetamine Law, Study Period and Data Collection Period

of the questions. Only minor changes in wording in the instruments were necessary after the pretest results were reviewed.

### The Telephone Interview

The telephone interview was designed to accomplish two objectives:

- (1) collection of descriptive information concerning the participatory status of every Duval County community pharmacy; and
- (2) acquisition of information detailing issues and response categories for the development of both questionnaires.

In this manner the telephone interviews served a dual purpose. First, that of a preliminary case study to enable the researcher to develop the best possible instrument in the shortest amount of time. And second, the interview achieved one of the study objectives, that of determining the degree of pharmacists' participation in the voluntary program.

The interviewer telephoned every licensed non-hospital community pharmacy in Duval County in 1979, asked for the pharmacist on duty, identified himself and his purpose, and asked the following sequence of questions:

- (1) Are you familiar with the Duval County project regarding the dispensing of amphetamines and methaqualone?
- (2) Does your pharmacy participate in this voluntary program?
- (3) What are your feelings or comments regarding this program?

The interviews were designed to be approximately five minutes in length. However, because the discussion format gave the pharmacists an opportunity to verbalize their opinions to someone interested and in perceived authority, they lasted an average of twenty-five minutes. The calls were made at random times throughout the day and week in order to

minimize any time-of-week or time-of-day bias in the data. As with all other aspects of the study, the anonymity of the respondents was assured.

### Questionnaire Design

One of the objectives of the interviews was to acquire information for the development of the questionnaires. Several of the comments made by the pharmacists indicated their reasons for choosing to participate in the program. One pharmacist, who was vehemently against the program, said he was "hassled to participate." Others hailed the program as "an effective means to decrease the inventory of violence," a "way to decrease robberies," and as "a tremendous success in eliminating forgeries." These opinions were used to develop a Likert-scale instrument examining practitioner attitudes as to the reasons pharmacists chose to participate in the program and on the effectiveness of the program in decreasing amphetamine and methaqualone usage.

The telephone interview was useful in gathering initial information about the pharmacists' opinions and perceptions of the Duval County program. This information was important in the development of pharmacists' and physicians' questionnaires. It also yielded an indication of the degree of cooperation which could be expected from pharmacists in the subsequent stages of this study. A compilation of the pharmacists' comments appears in Appendix I.

### The Pharmacists' Questionnaire

The pharmacists' questionnaire was designed to elicit information in order to accomplish the following objectives:

- (1) to determine the extent of knowledge, as measured by accuracy and degree of precision, possessed by pharmacists regarding the Duval County program;
- (2) to identify factors which influenced the participatory status of the pharmacies;
- (3) to examine pharmacists' attitudes toward the Duval County program and their perceptions regarding its success or failure; and
- (4) to determine the extent of knowledge, as measured by accuracy and degree of precision, possessed by pharmacists regarding Florida's amphetamine law.

The pharmacists' questionnaire included additional questions regarding their perceptions as to why other pharmacists participated in the Duval County program, physician responses to the program, expansion of the program, and general drug abuse prevention measures. In addition, there were several questions which classified pharmacists as to their number of years in practice, association memberships, and pharmacy ownership. A space for comments was provided.

Rough drafts of the questionnaire were pretested with Gainesville pharmacists as respondents. The final draft was tested on nine pharmacists in a graduate seminar at the University of Florida College of Pharmacy, where each person was asked to evaluate the draft for meaning and clarity of the questions. The final questionnaire, which was administered to the pharmacists, appears in Appendix II. The pretest results were not included in the final data set.



### The Physicians' Questionnaire

The physicians' questionnaire was designed to elicit information in order to accomplish the following objectives:

- (1) to determine the extent of knowledge, as measured by accuracy and degree of precision, possessed by physicians regarding the Duval County program;
- (2) to identify the physicians' attitudes toward the Duval County program;
- (3) to determine the physicians' attitudes toward amphetamine usage; and
- (4) to determine the extent of knowledge, as measured by accuracy and degree of precision, possessed by physicians regarding Florida's amphetamine law.

The physicians' questionnaire contained inquiries about their drugs of choice for five conditions for which amphetamines could be prescribed during the following time periods; pre-Duval County program (1977), post-Duval County program (1979) and after Florida's new amphetamine law became effective (1981). The questionnaire also sought to identify physicians' knowledge and understanding of the specifics of the Duval County program.

Additionally, the survey included attitudinal questions regarding the degree of success of the program, expansion of the program and general drug abuse prevention measures. Many of the questions in the physicians' survey were identical to those contained in the pharmacists' survey, so that attitudes of these two groups of practitioners could be compared. Also, several questions were included so that physicians could

be categorized as to age, degree designation (M.D. or D.O.), speciality and gender. A space for comments was provided.

The questionnaire was mailed to fifty randomly selected Jacksonville physicians as a pretest. Stamped return envelopes were included to increase the response rate. Forty-two percent of the questionnaires were returned, providing an estimate of the response rate which could be expected for the final survey. The two questions which the pretest showed to be ambiguous or unclear, were modified. Only a few minor changes in wording were necessary. The pretest results were included in the final data set. The questionnaire in its final form is provided in Appendix IV.

A cover letter which accompanied the questionnaire explained its purpose and importance and assured the anonymity of the respondents. The cover letter is found in Appendix III.

A roster of licensed physicians in Duval County was obtained from the Department of Professional Regulation for the years 1977 and 1979. The final survey instrument was mailed to every osteopathic and allopathic physician who had been identified as potential amphetamine or methaqualone prescribers during the entire time period covered by the study and who were not included in the pretest. Potential prescribers included general practitioners and most physician specialists. However, urologists, radiologists, anesthesiologists, ophthalmologists, orthopedic surgeons, dermatologists and plastic surgeons were excluded from the study on the basis that they would seldom, if ever, need to prescribe the drugs in question. Because the issues involved were most likely not relevant to the practice of these physicians, they were excluded from the study population. The potential prescriber group totaled 346 additional physicians.

### The Prescription Review

The prescription review of Duval and Alachua County community pharmacies was designed to collect data necessary to accomplish the following objectives:

- (1) to describe and to compare dispensing behaviors for amphetamines, phenmetrazine, methylphenidate, and methaqualone in Duval County prior to and during the Duval County program; and
- (2) to describe and to compare dispensing behaviors for the same four drugs during the same time period in a control county.

An audit form was designed to collect the following information pertaining to the prescription:

- (1) the month the prescription was filled;
- (2) the year the prescription was filled;
- (3) the identity of the drug product prescribed (use of a two-digit code);
- (4) the quantity of the drug product prescribed;
- (5) the selling price of the drug product prescribed; and
- (6) the verification of the prescription's validity (if present).

The identity of the drug product prescribed was recorded through the use of a two-digit coding system developed by the researcher (see Figure 5). The complete list of codes for all pertinent drug products appears in Appendix V. The drug product coding system provided a means for quickly categorizing the products dispensed. Each different class of drug was assigned a chemical category code (e.g., dextroamphetamine = 7, amphetamine-combination products = 5). Specific product codes were included within each chemical category for identification of each of the different products. For example, 3 was the chemical category code for



AB Drug Product = Chemical Category Code + Specific Product Code

- 11 = Ritalin® 5 mg tablets
- 12 = Ritalin® 10 mg tablets
- 13 = Ritalin® 20 mg tablets

Figure 5. Drug Product Coding System - An Illustrative Key

methaqualone and within this class were the following specific products; 32-Quaalude® 300 mg, 34=Sopor® 300 mg, 36=Parest® 400 mg.

An easily read form for keypunching was developed as the most efficient means for expediting the data processing. A copy of this form appears in Appendix VI.

#### Auditor Qualifications for Data Collection

The data was collected by two graduate students who were registered pharmacists, each with at least six years of practical pharmacy experience. Each had skills in evaluative research methodology. These qualifications were deemed necessary for the accurate and reliable collection of the technical information required for this project.

Both auditors had previously completed an auditors' training program for a related project and had many hours of data collection experience. To assist the auditors and to assure complete data collection, a procedural guide for data collection was developed.

The review method employed had been used by both auditors in previous audits. They also had prior experience in auditing pharmacies of varying ownership categories in Jacksonville. These included independents (one-store pharmacies), small chains (two to ten pharmacies) and large chains (ten or more pharmacies).

In order to minimize inaccuracies due to auditor fatigue, not more than two pharmacies were audited in any one day. In addition to gathering data from prescription files, the auditor was also responsible for making sure that the pharmacist on duty completed the questionnaire. The audits were performed at random times throughout the day and week in order to minimize any time-of-day or time-of-week bias in the data.

The audit process was fully explained to all pharmacists when the initial telephone contact was made. They were assured that the identity of the participating pharmacies, as well as the information collected from the patient records, would remain anonymous.

### Sampling Methods

An evaluation of the experience under the Duval County program first required that the pertinent prescriptions and Schedule II prescriptions be sampled in order to extrapolate the analysis to a county-wide finding. Since the total number of amphetamine, methylphenidate, phenmetrazine, and methaqualone prescriptions dispensed in Duval County and their distribution among pharmacies was not known, the sampling unit became the individual pharmacy. Because only licensed community pharmacies are authorized to dispense prescriptions to out-patients, only non-hospital community pharmacies were included in the sample. Hospital pharmacies that had a combination Institutional Class II/Community Pharmacy permit were deleted from the sampling list because the program was not designed for their category and because they traditionally dispense an insignificant number of prescriptions for the drugs included in the study.

A list of community pharmacies was obtained from the Department of Professional Regulation. There were 104 licensed community pharmacies in Duval County in 1979 (Duval County and its neighboring counties are shown on a map in Figure 6). Ownership of these pharmacies was classified according to the following guidelines: (1) independent - when only one pharmacy was owned, (2) small chain - when two to ten pharmacies have a common ownership, and (3) large chain - when more than ten pharmacies have a common ownership. Participatory status of each of the 104 pharmacies was determined from the telephone interviews and was classified as follows:

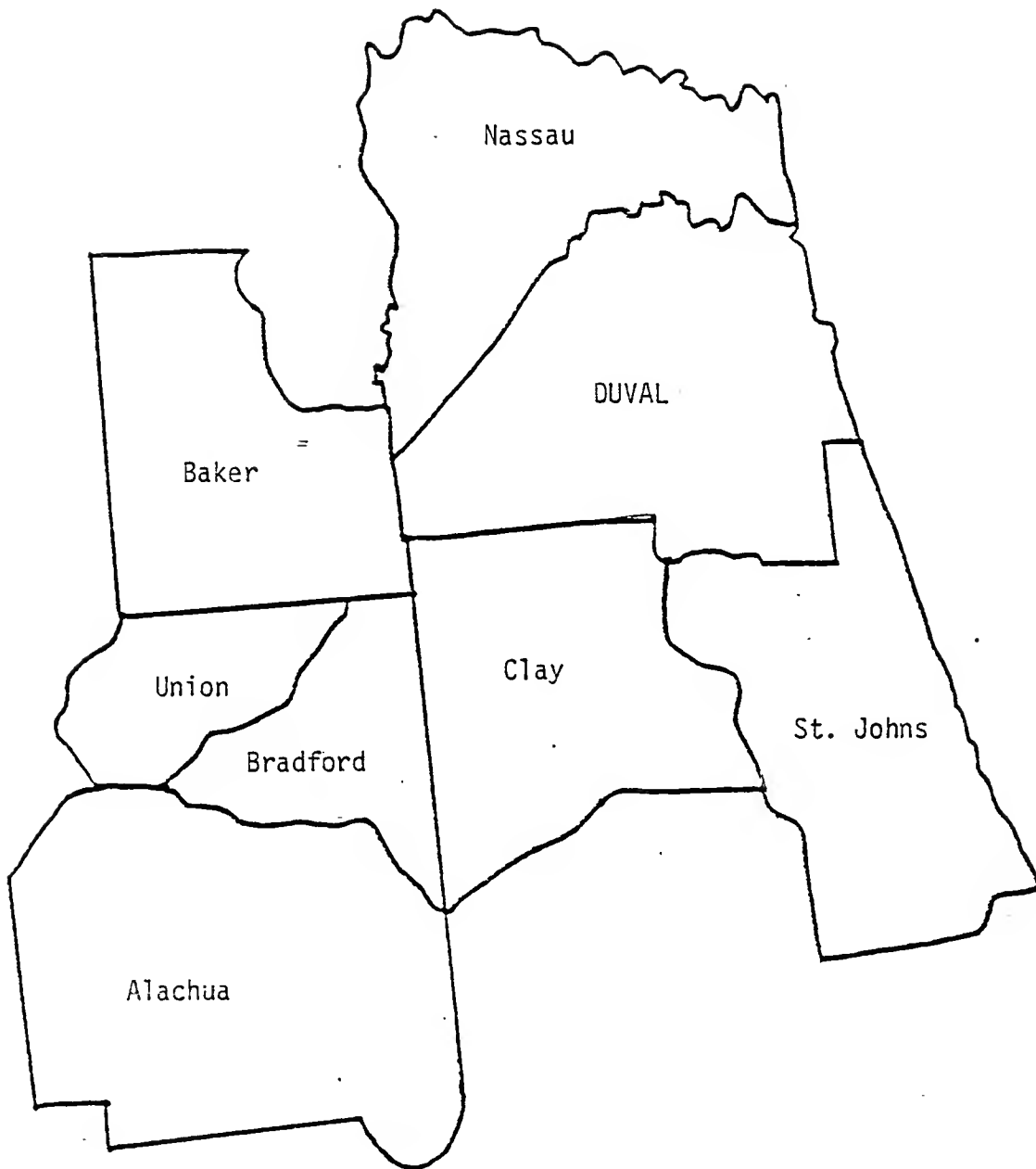


Figure 6. Duval and Neighboring Counties - A Geographical Key

(1) participating - pharmacist stated that the pharmacy participated in the Duval County program, (2) non-participating - pharmacist stated that the pharmacy had not participated in the Duval County program, and (3) partially participating - pharmacist stated that the pharmacy only participated for its non-regular customers.

These ownership and participatory parameters were established to control for these potentially important factors and are not sampling strata. It might be that the levels of these factors would impact on the evaluated success of the Duval County program. They are characteristics of respondents - independent non-varying factors.

In this study, we are examining an overall effect, not the differences among the groups defined by ownership or participation. But to guarantee that the county-wide effect was examined, it is important that all classifications are represented. The differences between the policies of large corporations and single entrepreneurs could be reflected by different levels of prescription reduction, as could the participatory status of the individual pharmacies.

Pharmacies selected for the sample had to meet the following inclusion criteria:

- (1) the pharmacy must have been in operation from December 1, 1976 to December 31, 1979; and
- (2) the auditor had to have access to the original Schedule II prescription records for that period of time.

#### Randomization Process

A simple random sample of thirty pharmacies was chosen. All Duval County pharmacies were sequentially numbered and a random number table



was used to select the sample pharmacies. A pretest of five of the randomly selected pharmacies was performed in order to test the audit procedure and to gather preliminary data for use in the sample size determination. These results are included in the final results. The sample size was based solely on calculations using finite population correction factors and pretest statistics of variance and mean. The decrease in the number of amphetamine prescriptions as a percentage of Schedule II prescriptions from 1977 to 1978 was 67.8 percent with a variance ( $S^2$ ) of 368.91 and a standard deviation ( $\sigma$ ) of 19.2. The goal was to be able to calculate the actual percentage of decrease to within five percent. Therefore, the range of meaningful difference ( $\beta$ ) to be detected was seven percent. According to The Basics of Biomedical Research Methodology by Marks [76:221] the calculations for sample size determination required the following calculation:

$$\Delta = \frac{\beta}{\sigma} = .36458 \quad \text{where: } \beta = \text{meaningful difference} \\ \sigma = \text{standard deviation}$$

Using this value of Delta, the sample size required to estimate the mean percentage decrease in amphetamine prescriptions with a confidence coefficient of 0.95 was determined from Table 9.3 in Marks' text [76:350]. The desired sample size calculated was twenty-eight, two additional pharmacies were sampled to ensure against the pretest pharmacies being non-representative of the population. Therefore, the universe is all non-hospital community pharmacies in Duval County ( $N = 104$ ).

#### Sample Attrition

All thirty pharmacies were initially contacted by means of telephone solicitation. The large chains often required a telephone consultation

with their District Supervisors and, where requested, an explanatory letter. Follow-up telephone calls were used to establish audit appointments. Only one of the thirty pharmacies did not meet established criteria. Of the remaining twenty-nine pharmacies, only one declined to participate. Two replacement pharmacies were chosen at random to return the total to thirty pharmacies.

Table 1 shows the cooperation rate of sampled pharmacies as categorized by ownership and participatory status. Of the thirty-one eligible pharmacies, thirty (97 percent) agreed to be audited. Because of the very high response rates in all six categories, bias due to non-response can be considered negligible.

#### Sample Representativeness

Table 2 presents the universe (Duval County pharmacies) and study sample by ownership category and participatory status. The percentage for both the study sample and the universe are very close. Table 3 details the participatory status of the universe and the study sample by ownership category. Both tables indicate the similarity between the two groups when comparing these characteristics. Thus, all cells in Table 3 for the universe are adequately represented in the sample. This indication of the representativeness of the sample to the population allows us to extrapolate the results of this study to the entire county.

#### Study Period

For every pharmacy audited, all Schedule II prescription records were reviewed within the defined study period. The study period was defined as follows:

TABLE 1

## Cooperation Rate of Pharmacies by Ownership Type and Participatory Status Category

Independent		Small Chain		Large Chain		Total	
Pharmacies Contacted	Pharmacies Audited	Pharmacies Contacted	Pharmacies Audited	Pharmacies Contacted	Pharmacies Audited	Pharmacies Contacted	Pharmacies Audited %
10*	9	8	8	14**	13	32	94

Participating		Partially Participating		Non-Participating		Total	
Pharmacies Contacted	Pharmacies Audited	Pharmacies Contacted	Pharmacies Audited	Pharmacies Contacted	Pharmacies Audited	Pharmacies Contacted	Pharmacies Audited %
19*,**	17	5	5	8	8	32	94

\*Pharmacy declined to be audited.

\*\*Pharmacy ineligible (records destroyed).

TABLE 2  
Duval County Pharmacies and Study Sample  
by Ownership Category and Participatory Status

Independent		Small Chain		Large Chain		Total	
Pharmacies	Sample	Pharmacies	Sample	Pharmacies	Sample	Pharmacies	Sample
41	9	24	8	38	13	104	30
(40%)	(30%)	(23%)	(27%)	(37%)	(43%)	(100%)	(100%)

Participating		Partially Participating		Non-Participating		Total	
Pharmacies	Sample	Pharmacies	Sample	Pharmacies	Sample	Pharmacies	Sample
58	17	18	5	28	8	104	30
(56%)	(56%)	(17%)	(17%)	(27%)	(27%)	(100%)	(100%)

TABLE 3  
Participatory Status of Duval County Pharmacies and Study Sample by Ownership Category

	Participating		Partially Participating		Non-Participating		Total
	Pharmacies	Sample	Pharmacies	Sample	Pharmacies	Sample	Sample
Independent	22	4	12	3	7	2	41 9
Small Chain	10	4	4	1	10	3	24 8
Large Chain	26	9	1	1	11	3	38 13
Total	58	17	18	5	28	8	104 30

- (1) December 1, 1976 to November 30, 1977; and
- (2) January 1, 1978 to December 31, 1979.

Detailed data were collected from this sample of prescriptions.

December 1, 1976 to November 30, 1977 was the year prior to the initiation of the program. The study period included the first two years after the program's beginning in order to measure any changes in the practitioner's responsiveness over time. December 1, 1977 to December 31, 1977 was specifically excluded because it was the month in which the Duval County program was initiated and because compliance was deemed to be minimal during the phase-in period.

The total number of Schedule II prescriptions dispensed within this period of time was tallied.<sup>6</sup> The legal requirement calling for the separate filling of Schedule II prescriptions made the task of counting them quicker and more accurate.

#### Response Variable

The response variable for this study is number of prescriptions (for amphetamines, methaqualone, phenmetrazine and methylphenidate) as a percentage of Schedule II prescriptions. This value was chosen instead of a comparison of the total numbers of prescriptions for these drugs for the three survey years, because this ratio adjusts the data by volume, thereby preventing any exaggerated weighting by high volume pharmacies.

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<sup>6</sup>In some instances, there was a misfiling of non-Schedule II prescriptions with the Schedule II prescriptions. These were not counted in the total. For those cases where Schedule II prescriptions might be misfiled in the regular files, it was deemed to be an unimportant and negligible event because if a legal authority (DEA or Board of Pharmacy) were to audit the same pharmacy, these misfiled prescriptions would be considered as missing inventory.

### Control Sample

Because of the large decreases in amphetamine prescription volume demonstrated by the pretest, it was decided to include a control county in the sample. This was necessary to control for any historical effects, other than the Duval County program, which might have impacted on the decrease found in the number of prescriptions. A non-contiguous county, Alachua County, was selected because of similar demographics, professionally active pharmacists, similar urban-rural blend, and large medical community. Economy of collection costs was also a consideration. There are twenty-eight community pharmacies licensed in Alachua County. Of these, twenty-two met the criteria established for Duval County pharmacies. A simple random sample of ten pharmacies was chosen because of time and resource constraints. All Alachua County pharmacies were sequentially numbered and a random number table was used to select the sample pharmacies.

For every control pharmacy audited, all Schedule II prescription records were sampled within the defined study period. Detailed data were collected from the control sample. For each prescription included in the control sample, information was obtained regarding the specific drug prescribed (strength, quantity, notations indicating verification). The total number of Schedule II prescriptions dispensed within the study period was tallied for each pharmacy.

For both the control sample and the Duval County sample, the total number of new prescriptions in each pharmacy for each of the three years of the study was documented.

### Summary of Data Collection Methodology

To summarize, thirty randomly selected community pharmacies (29 percent) in Duval County were sampled along with ten randomly selected control community pharmacies (45 percent) in Alachua County. All Schedule II prescriptions were reviewed and all amphetamine, methylphenidate, phenmetrazine, and methaqualone prescriptions for the three year period were noted. Finally, questionnaires were distributed to thirty Jacksonville pharmacists and 396 Jacksonville physicians.

### Data Analysis Methodology

In order to fulfill the stated objectives of this study, data and descriptive information were collected through the use of the following instruments:

- (1) telephone interviews;
- (2) practitioner questionnaires; and
- (3) a prescription review.

These results were sorted and categorized into variables in order to analyze and to compare them in accordance with the data analysis plan. A brief synopsis of this two-part plan follows:

- (1) Evaluation of the program's outcome. This was accomplished through the utilization of the results from the prescription review. The primary variables studied in this section are the number of pertinent drug prescriptions as a percentage of Schedule II prescriptions and the annual average of pertinent drug prescriptions per pharmacy; and
- (2) Examination of the participants' attitudes. This was accomplished through the utilization of the results from the



practitioner questionnaires and the telephone interview.

The primary variables studied in this section are accuracy ratings for each practitioner and attitudinal ratings derived from the Likert-type questions.

The next chapter addresses in detail part one of this plan, the evaluation of the program's outcome, and discusses the results obtained from the prescription review. Part two, the examination of the participants' attitudes and actions in implementing the goals of the program, is discussed in detail in Chapter V.

## CHAPTER IV

### OUTCOMES OF THE DUVAL COUNTY PROGRAM

As noted in Chapter II, the first step in an implementation study is an evaluation of the program's outcome. Accordingly, prescription records were audited in the sample pharmacies in Alachua and Duval counties for a three-year period which began one year before the program went into effect. This chapter discusses the results obtained from the review and summarizes the outcomes of the Duval County program.

One objective of the prescription review was to retrieve information so that the dispensing patterns for amphetamines, methaqualone, phenmetrazine, and methylphenidate during the study period in both the experimental and control counties could be described and compared. Other objectives included the examination of pharmacist-initiated verification activities and the voluntary program's coverage level (participation percentage).

The sample of pharmacies from both counties is a random one. Table 4 describes the sample by location, practice setting, ownership category and pharmacists' gender. Table 5 presents volume characteristics for new prescription and Table 6 presents the Schedule II prescription volume as a percentage of new prescription volume for the sampled pharmacies.

The results of the prescription review are presented in the following four sections:

- (1) Prescription Trends;
- (2) Prescribing Behaviors;

TABLE 4

Characteristics of Pharmacies Participating in Study

County	Pharmacy Location				Practice Setting				Ownership Category			Pharmacists' Gender	
	Urban/Downtown	Suburban Neighborhood	Rural	Medical Building	Part of Department of Discount Store	Free Standing Community Pharmacy	Mail	Large Chain	Small Chain	Independent		Female	Male
Duval	16 (53.3%)	13 (43.3%)	1 (3.4%)	3 (10.0%)	14 (46.7%)	11 (36.7%)	2 (6.6%)	13 (43.3%)	8 (26.7%)	9 (30%)		4 (13.3%)	26 (86.7%)
Alachua	4 (40%)	5 (50%)	1 (10%)	1 (10%)	5 (50%)	3 (30%)	1 (10%)	5 (50%)	5 (50%)	0 (0%)		5 (50%)	5 (50%)

TABLE 5  
New Prescription Volume by Year of Sampled Pharmacies

New Prescription Volume	Duval County			Alachua County		
	1977	1978	1979	1977	1978	1979
> 30,000	3	4	2	1	1	0
15,000-30,000	5	5	7	6	6	7
10,000-14,999	10	8	11	1	1	1
5,000- 9,999	9	10	6	1	1	1
< 5,000	3	3	4	1	1	1
Total	30	30	30	10	10	10

TABLE 6

## Schedule II Prescriptions as a Percentage of New Prescriptions

		Median	Mean	Standard Error		Number of Values Greater than the Mean
Duval County	1977	5.89	5.24	0.3	12	(40%)
	1978	4.63	4.96	0.3	14	(47%)
	1979	4.62	5.25	0.4	13	(43%)
Alachua County	1977	2.83	3.16	0.5	4	(40%)
	1978	2.53	2.89	0.4	4	(40%)
	1979	2.79	2.79	0.3	5	(50%)
<hr/>						
Percentage Range	Duval County			Alachua County		
	1977	1978	1979	1977	1978	1979
1.5 - 3.5	1	6	5	8	8	9
3.6 - 3.9	1	5	6	0	1	0
4.0 - 5.8	16	11	8	1	1	1
5.9 - 6.9	6	3	6	1	0	0
7.0 -13.0	6	5	5	0	0	0

- (3) Verification Activities; and
- (4) Participation Level.

### Prescription Trends

The first part of the Duval County program's outcome evaluation encompasses an examination of the trends in prescription dispensing which occurred during the study period. The two drugs which were included within the scope of the Duval County program, amphetamine and methaqualone, are the major focus of the outcome evaluation. Methylphenidate was not included in the program, but because it is a Schedule II sympathomimetic agent and legally is considered to have an abuse potential similar to that of the amphetamines [77] it was included in the study so that its dispensing patterns could be examined and compared with those of the other two drugs.

Figure 7 shows the raw data tabulations for the experimental county. These figures provide the basis for all further analysis and discussion.

The first set of variables that was used to document the program's outcome is amphetamine or methaqualone prescriptions as a percentage of Schedule II prescriptions. Figure 8 provides a graphic representation of amphetamine prescriptions as a percentage of Schedule II prescriptions. In 1978 amphetamines accounted for only 3.5 percent of the Schedule II prescriptions, which represents a decrease of 73.3 percent from the year prior to the initiation of the Duval County program, (1977). The decrease for the control county over the same period of time was 27.3 percent, which indicates that the voluntary program alone could have been responsible for a decrease of up to 46.0 percent in legitimate amphetamine prescriptions in the experimental county after its initiation.

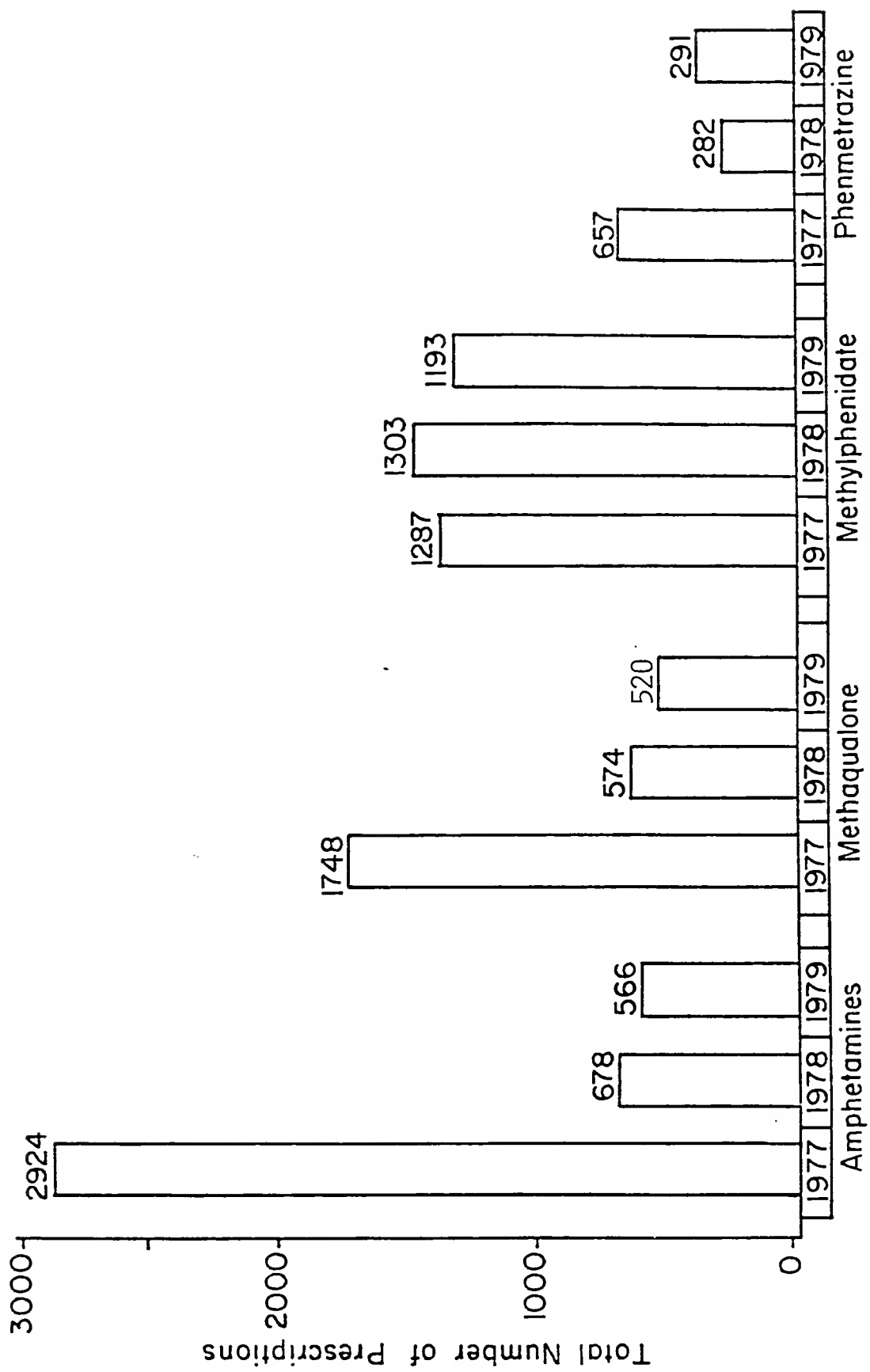


Figure 7. Raw Data Tabulation for Duval County

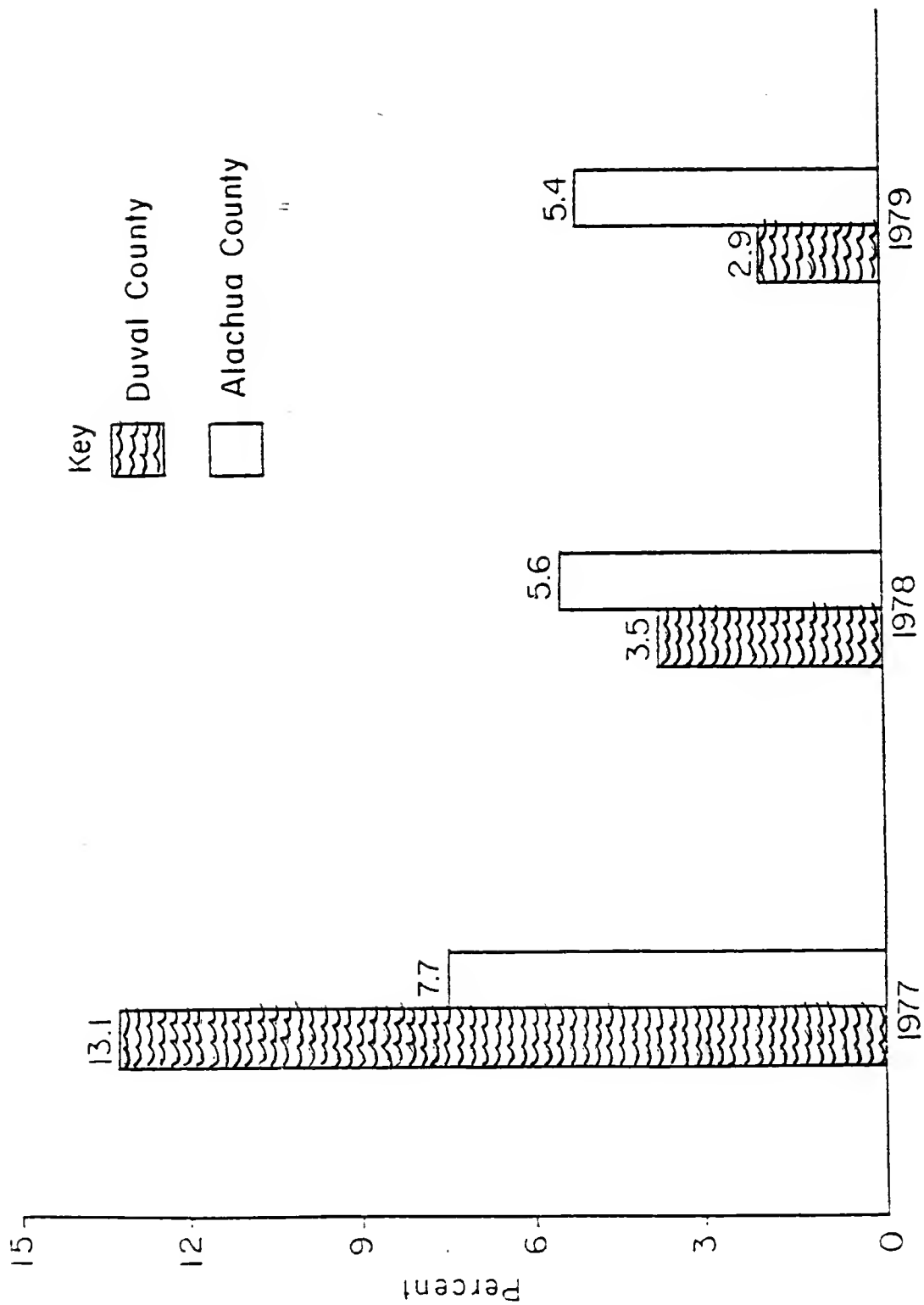


Figure 8. Amphetamine Prescriptions as a Percentage of Schedule II Prescriptions



The dramatic decrease in amphetamine prescriptions exhibited in Duval County when compared to the decrease in Alachua County, indicates that the program was successful in reducing the number of prescriptions for amphetamines. The figures for 1979 were lower than those for 1978 in both counties. These figures indicate that the program's effect was not temporary, but rather that it had a lasting behavioral modification effect on both pharmacists and physicians in regard to the dispensing and prescribing of amphetamine and methaqualone drug products.

The variable, methaqualone prescriptions as a percentage of Schedule II prescriptions, is presented in Figure 9. For Duval County, the 1978 results showed a 67.2 percent decrease from the 1977 results, while in Alachua County, the decrease was only 36.7 percent. Again, as with the amphetamine variable, the 1979 results in both samples were below those for 1978.

The variable, methylphenidate prescriptions as a percentage of Schedule II prescriptions, is compared with the first two variables, amphetamine and methaqualone prescriptions, inasmuch as methylphenidate was subject to the same federal and state controls as the other two drugs, but it was not included in the Duval County program. Figure 10 details the results for methylphenidate. There was no significant difference<sup>7</sup> between the results for any two years of the study period, however, the slight increase in the percentage of methylphenidate prescriptions can be attributed to a concomitant decrease in the total number of Schedule II prescriptions. These results help confirm the findings that the Duval

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<sup>7</sup>Unless otherwise noted, all references to findings of statistical significance in this chapter are based on the Z-test.

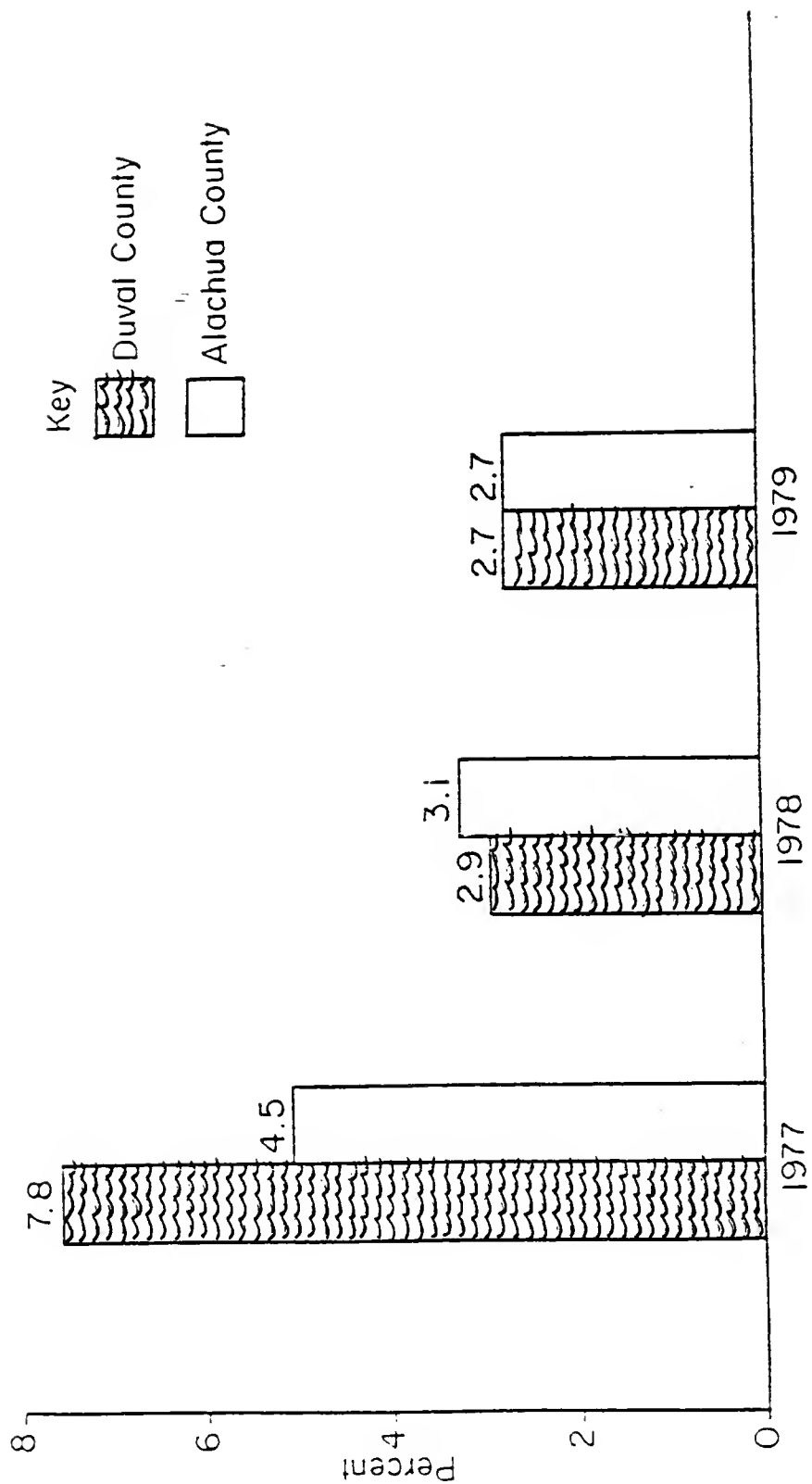


Figure 9. Methaqualone Prescriptions as a Percentage of Schedule II Prescriptions

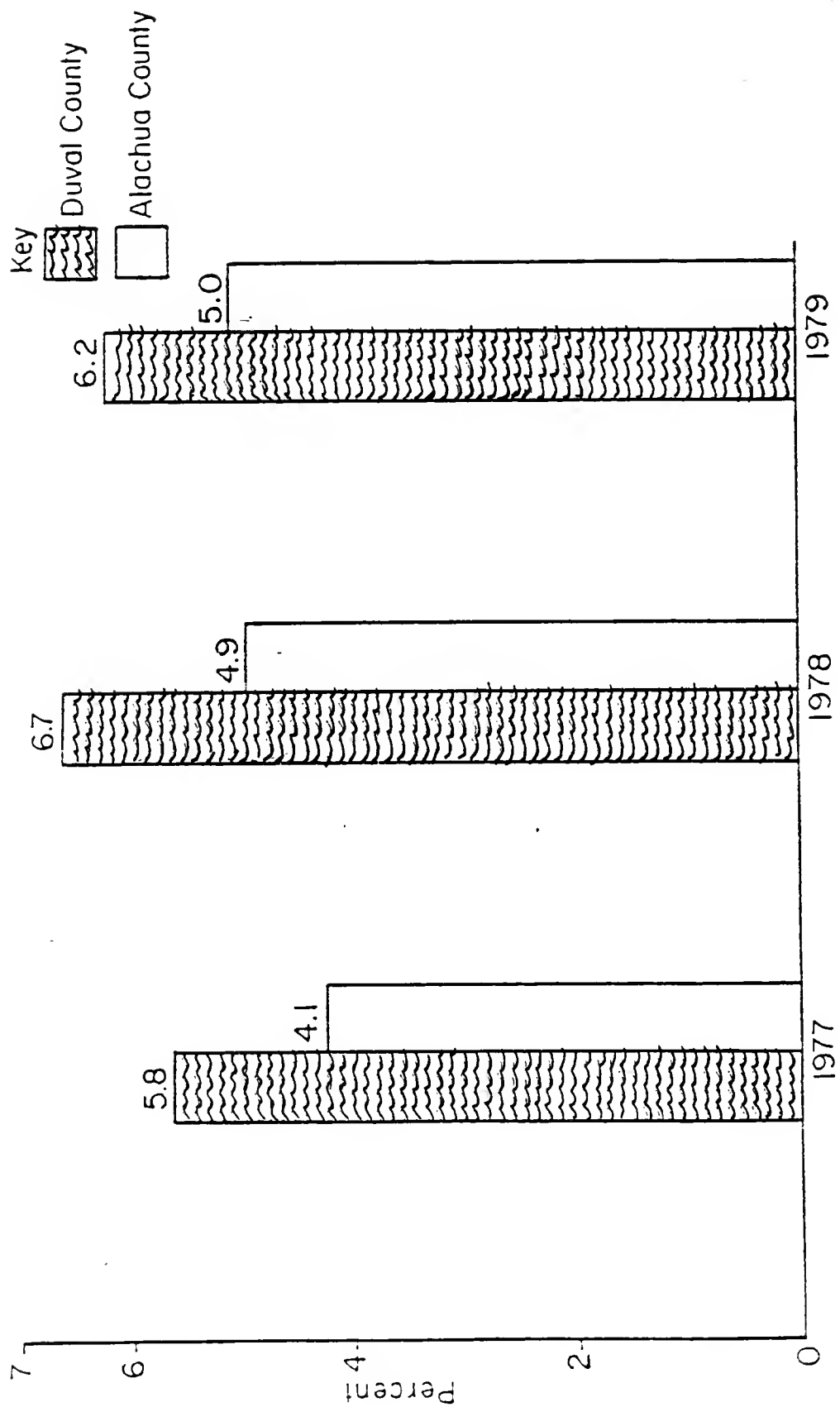


Figure 10. Methylphenidate Prescriptions as a Percentage of Schedule II Prescriptions

County program was the *raison d'être* behind the decrease in the number of methaqualone and amphetamine prescriptions.

The second set of variables that was used to document the success of the program was the average annual prescription volume for amphetamines and methaqualone per pharmacy. Figure 11 presents the average annual amphetamine prescription volume per pharmacy for Duval and Alachua Counties. There was a 76.8 percent decrease for amphetamines between 1977 and 1978 in Duval County, as opposed to a 32.5 percent decrease in the control county. There was a further, but slight, decrease in 1979 which again indicates that the Duval County program had a lasting effect on physicians and pharmacists.

The annual methaqualone prescription volume per pharmacy appears in Figure 12. The results were identical to those presented by the first variable for methaqualone and show a decrease between 1977 and 1978 both in Duval County (67.2 percent) and in Alachua County (36.7 percent). The results obtained for 1979 demonstrated a continuing decrease from the 1977 figures.

For the second set of variables, methylphenidate again was used as a control, since it was not included in the voluntary program. Figure 13 presents the average annual methylphenidate prescription volume per pharmacy. There was very little change from year to year for either county. Methylphenidate prescription volume has remained constant during the study period.

To summarize, there was a significant decrease in the number and volume of both amphetamine<sup>3</sup> and methaqualone<sup>9</sup> prescriptions, as measured

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<sup>3</sup>p < .0001

<sup>9</sup>p < .001

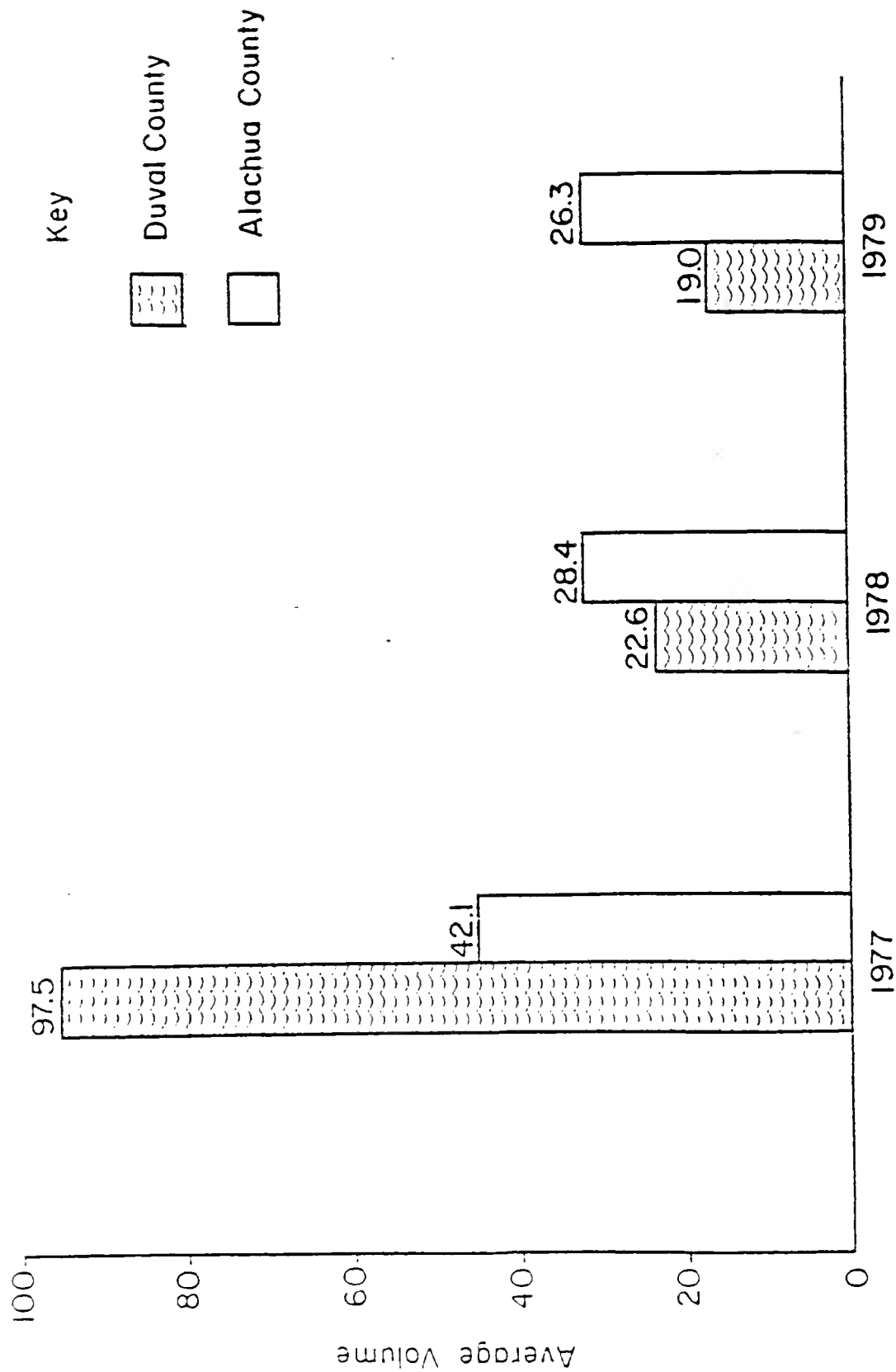


Figure 11. Average Annual Amphetamine Prescription Volume Per Pharmacy

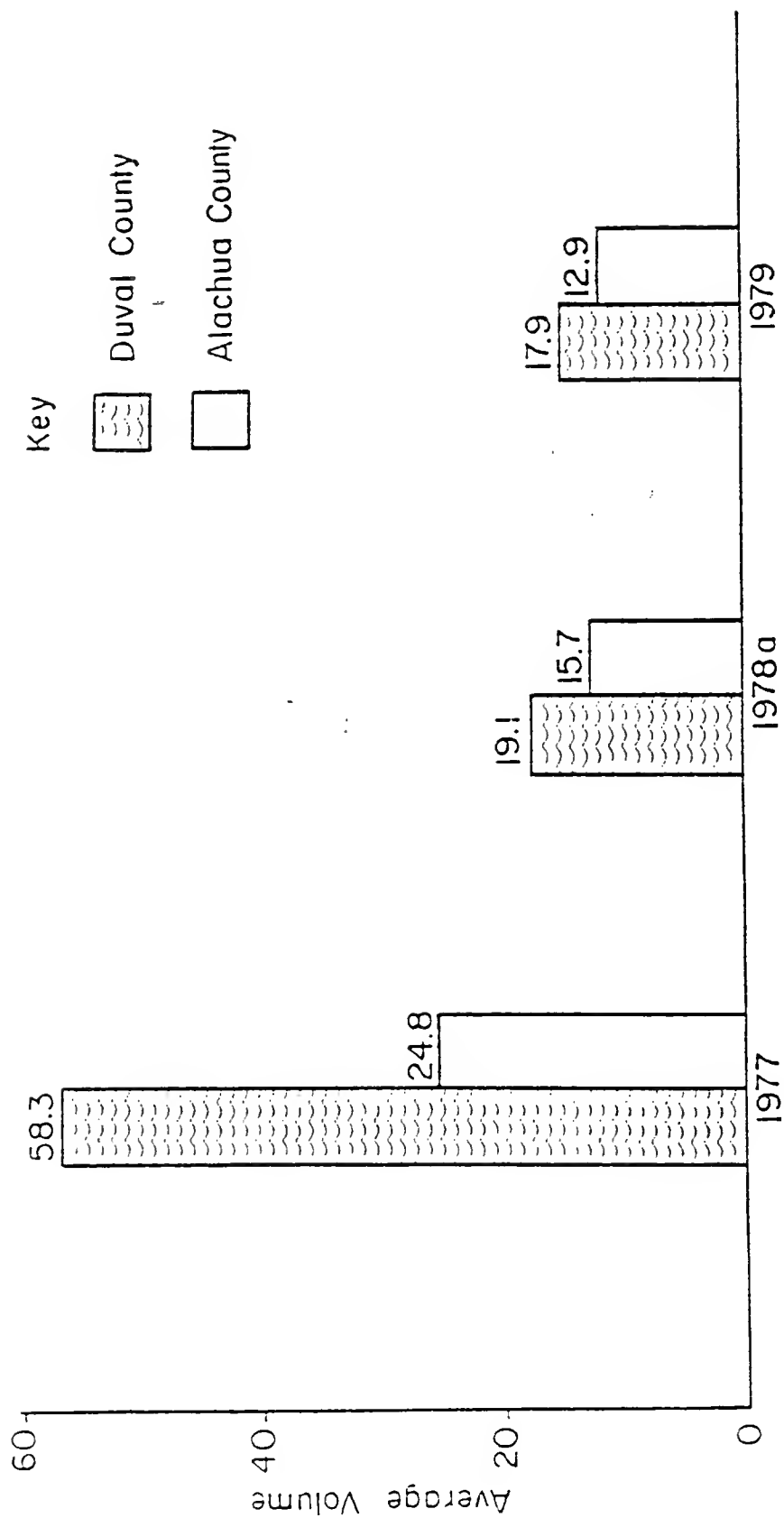


Figure 12. Average Annual Methaqualone Prescription Volume Per Pharmacy

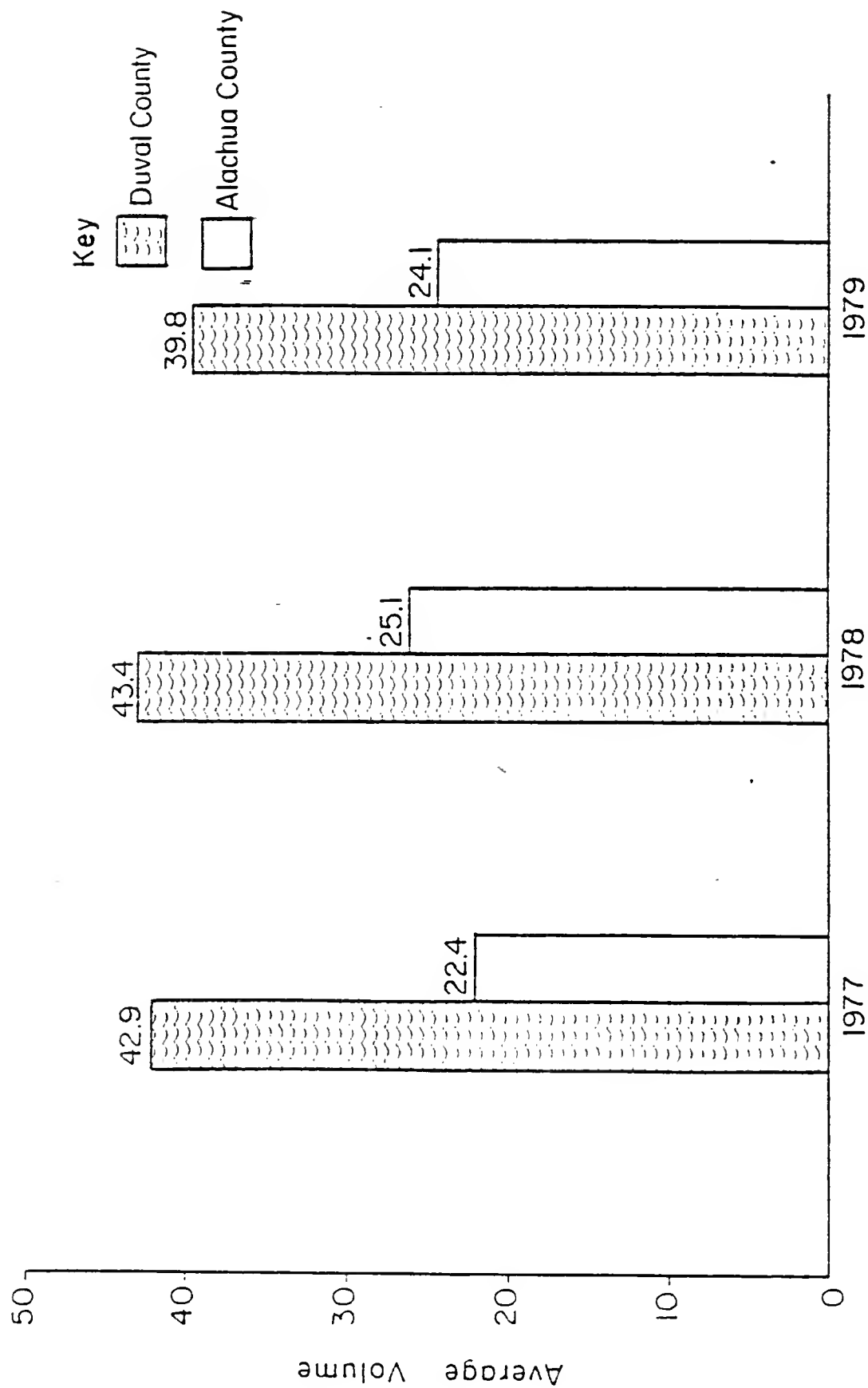


Figure 13. Average Annual Methylphenidate Prescription Volume Per Pharmacy

by the average volume per pharmacy and as a percentage of Schedule II prescriptions, after the initiation of the voluntary program. The decrease for amphetamine products was 76.8 percent and for methaqualone, 67.2 percent. The volume decreases in Duval County were significantly different from those in the control county, which were 32.5 percent and 36.7 percent,<sup>10</sup> respectively. The decrease in volume, which came about during 1978, continued throughout 1979.

The control drug, methylphenidate, was also monitored during the study period. Methylphenidate was subject to the same federal and state controls as amphetamine and methaqualone, but was not included in the Duval County program. The number of prescriptions for methylphenidate varied very little in either county during the study period. The reduction in the number of amphetamine and methaqualone prescriptions observed in the experimental county was much greater than that observed in the control county. The reduction in the volume of amphetamine and methaqualone prescriptions when compared with the static prescription volume for the control drug, methylphenidate, leads to the following conclusion:

The Duval County program was successful in decreasing the availability of legally procured amphetamine and methaqualone prescriptions.

### Prescribing Behaviors

The second part of the program's evaluation entails an examination of physicians' prescribing behaviors during the study period. Phenmetrazine is the fourth drug which was included in the prescription review. It is included in this section because of the interesting results that were observed. Phenmetrazine, like amphetamine and methylphenidate, is

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<sup>10</sup> $p < .0001$  and  $p < .001$ , respectively.



a Schedule II sympathomimetic agent and is subject to the same federal and state controls and, like methylphenidate, was not included in the Duval County program. Nevertheless, as Figures 14 and 15 demonstrate, there was a large reduction in the number of phenmetrazine prescriptions dispensed in the experimental county<sup>11</sup> after the program's initiation and an unexpected increase in phenmetrazine prescriptions in the control county. The results for 1979 showed a continuation of this unexpected trend for Duval County.

One explanation for this phenomenon is found in the results obtained from the pharmacists' and physicians' questionnaires: thirty-nine (32.3 percent) of the physicians and twenty-one (72.4 percent) of the pharmacists in Duval County believed that phenmetrazine was included as part of the voluntary program. The results of the questionnaires are discussed in detail in Chapter V.

Table 7 shows the annual rankings for the drug products being evaluated. Major changes in rank position are exhibited by amphetamine products: there were five products listed in 1977 and only two products each in 1978 and 1979. Methylphenidate (Ritalin®) products, moved up in rank between 1977 and 1978. These positional changes do not reflect an increase in the number of methylphenidate prescriptions, but rather, they reflect a substantial decrease in the number of prescriptions for amphetamine and methaqualone products. The 1979 rankings exhibited no major changes from those of 1978. Therefore, the findings that the program had brought about lasting behavioral modifications for both physicians and pharmacists regarding amphetamine, methaqualone and phenmetrazine drug products was reinforced.

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<sup>11</sup><sub>p</sub> < 0.05

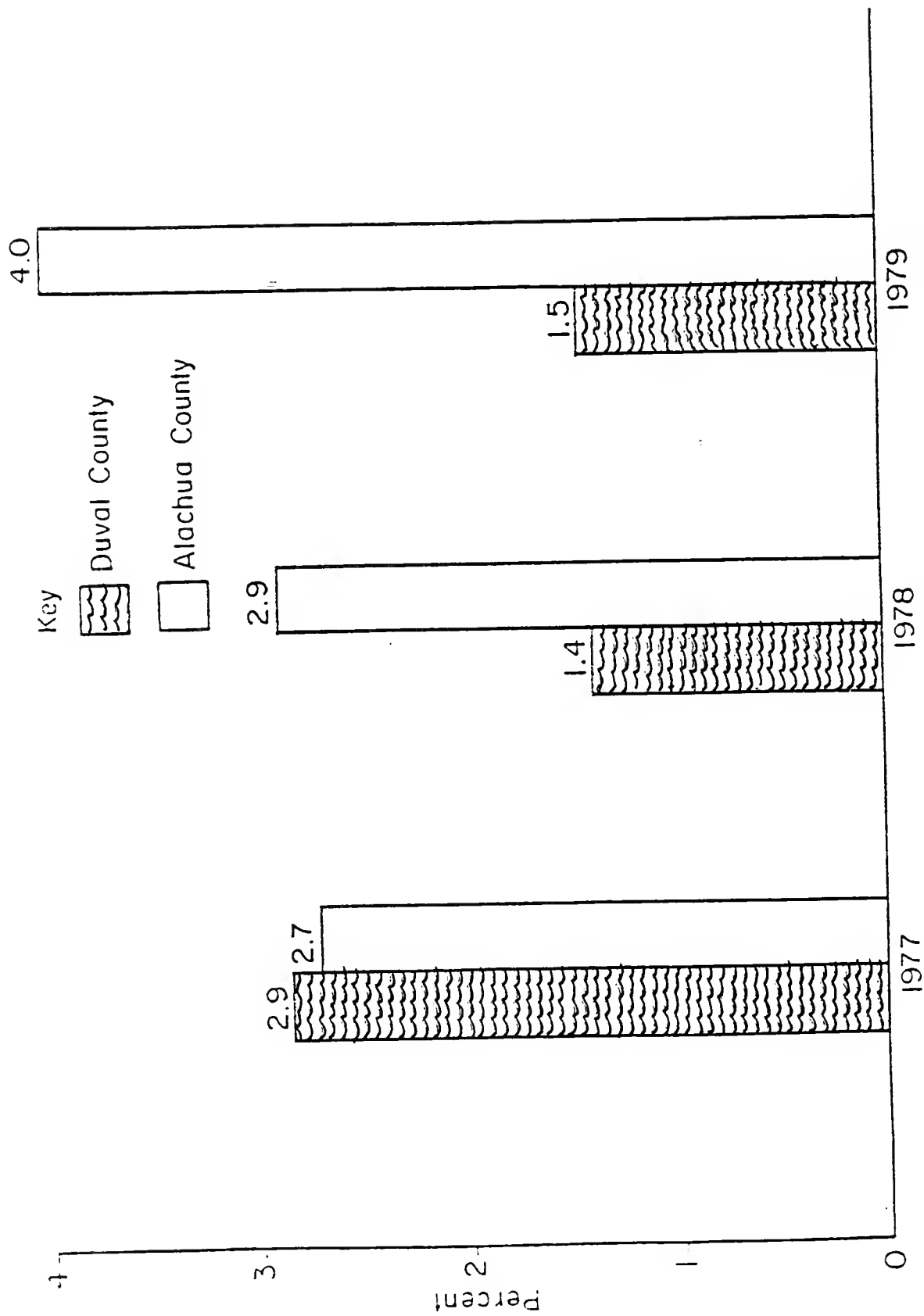


Figure 14. Phenmetrazine Prescriptions as a Percentage of Schedule II Prescriptions

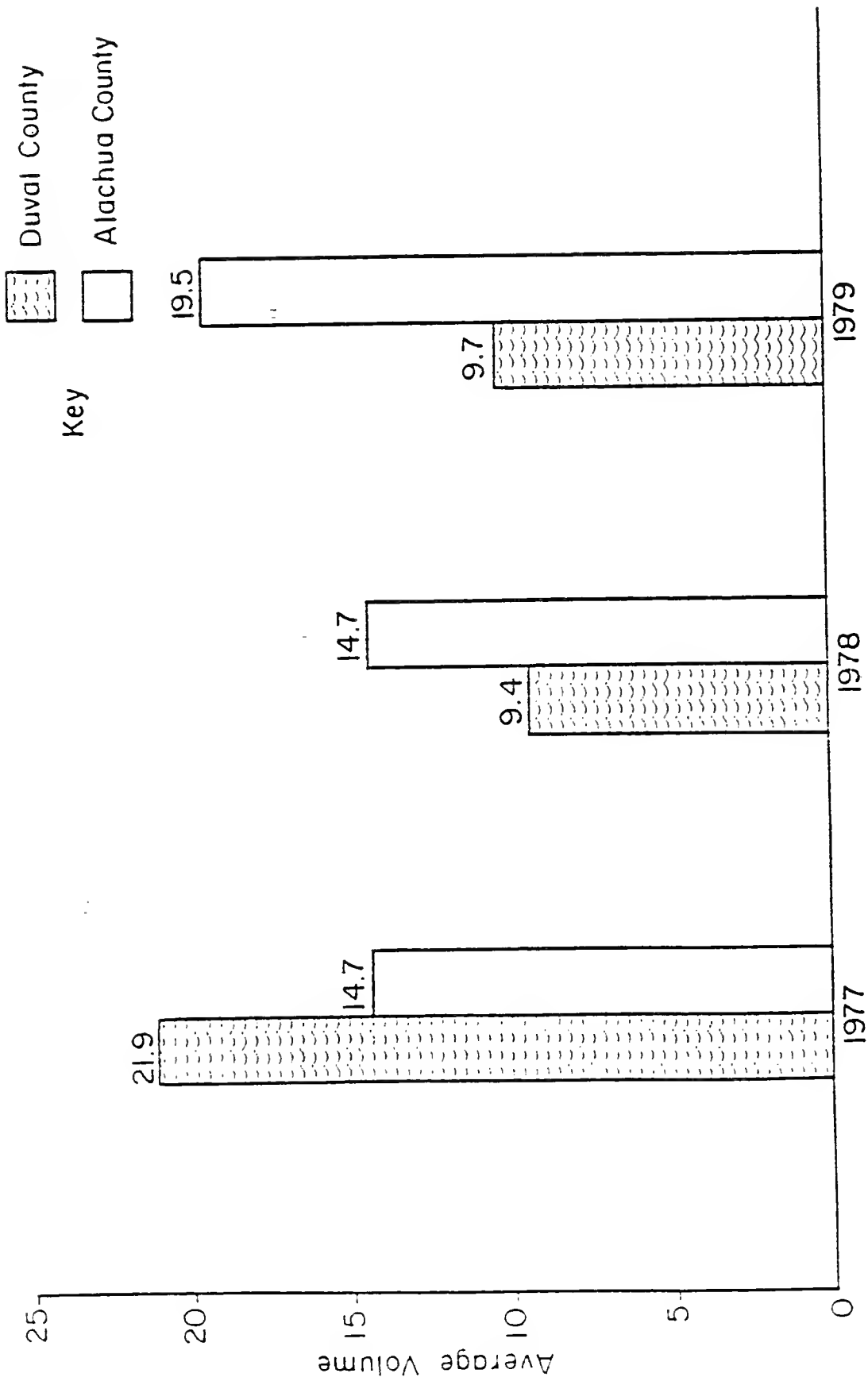


Figure 15. Average Annual Phenmetrazine Prescription Volume Per Pharmacy

TABLE 7

## Annual Rankings for Studied Drug Products in Duval County\*

Rank	1977		1978		1979	
	Drug Product	Annual Volume	Drug Product	Annual Volume	Drug Product	Annual Volume
1	Eskatrol <sup>®</sup> \$	1210	Ritalin <sup>®</sup> 10 mg #	686	Ritalin <sup>®</sup> 10 mg #	660
2	Quaalude <sup>®</sup> 300 mg Ø	1190	Ritalin <sup>®</sup> 5 mg #	360	Ritalin <sup>®</sup> 5 mg #	312
3	Biphetamine-20 <sup>®</sup> \$	1126	Preludin <sup>®</sup> 75 mg **	305	Preludin <sup>®</sup> 75 mg **	301
4	Preludin <sup>®</sup> 75 mg **	752	Quaalude <sup>®</sup> 300 mg Ø	303	Quaalude <sup>®</sup> 300 mg Ø	277
5	Ritalin <sup>®</sup> 10 mg #	693	Ritalin <sup>®</sup> 20 mg #	291	Ritalin <sup>®</sup> 20 mg #	268
6	Sopor <sup>®</sup> 300 mg Ø	546	Sopor <sup>®</sup> 300 mg Ø	264	Sopor <sup>®</sup> 300 mg Ø	248
7	Ritalin <sup>®</sup> 5 mg #	420	Eskatrol <sup>®</sup> \$	240	Eskatrol <sup>®</sup> \$	159
8	Ritalin <sup>®</sup> 20 mg #	261	Biphetamine-20 <sup>®</sup> \$	114	Dexedrine <sup>®</sup> 5 mg \$	101
9	Dexamy1 #2 <sup>®</sup> \$	249				
10	Dexedrine <sup>®</sup> 5 mg \$	228				
11	Sopor <sup>®</sup> 150 mg Ø	118				
12	Biphetamine-12.5 <sup>®</sup> \$	101				

\*For those products which accounted for a minimum of 100 prescriptions per annum.

KEY: \$ = Amphetamine product; Ø = Methaqualone product; # = Methylphenidate product; and \*\* = Phenmetrazine product.

Under the guidelines of the Duval County program, physicians were requested to prescribe amphetamines and methaqualone in stock-size packaging in order to minimize the retention by pharmacies of partially filled containers. Table 8 presents stock-size package prescribing activities for Duval County during the study period. Although there was a decrease in the total number of prescriptions for stock-size packages between 1977 and 1978, there was a significant increase in the percentage of prescriptions for stock-size packages of amphetamines<sup>12</sup> and methaqualone.<sup>13</sup> There was a 62.0 percent increase in stock-size package prescribing activities in 1978 and this trend continued for both drugs during 1979. The program participants should have been aware of the status of each drug as a list of the products included in the program and information regarding stock-size packaging was available and could be attained by all pharmacists and physicians from their respective professional associations.

In summary, it was found that the prescribing behaviors of physicians were altered after the initiation of the Duval County program. First, there was a substantial change in the prescribing of phenmetrazine in Duval County that paralleled the results obtained for amphetamine and methaqualone. These results can be attributed to the belief held by a substantial number of pharmacists and physicians (including the President of the Duval County Medical Society) that phenmetrazine was included within the program's scope. The Duval County decrease contrasted sharply with the increase in phenmetrazine prescriptions in the control county

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<sup>12</sup><sub>p</sub> < 0.01

<sup>13</sup><sub>p</sub> < 0.01

TABLE 8

Stock-Size Package Prescribing Activities  
for Methaqualone and Amphetamines in Duval County

Drug	Year	Stock-size Package Prescriptions	Total Prescription Volume	Stock-size Packaging Percent
Amphetamines	1977	616	3456	17.8
	1978	363	781	46.8
	1979	321	634	50.6
<hr style="border-top: 1px dashed black;"/>				
Methaqualone	1977	161	2061	7.8
	1978	135	660	20.6
	1979	129	597	21.6

during the study period. Second, there was a dramatic rearrangement of the rankings of the most frequently prescribed drugs in the experimental county, with amphetamine and methaqualone drug products dropping from the top three positions as a result of the large decrease in the number of prescriptions for such drugs after the program began. And third, there was a significant increase in the prescribing of stock-sized packaging for amphetamine and methaqualone in Duval County during the program.

These results lead to the following conclusion:

The Duval County program successfully altered the prescribing behaviors of physicians. This behavioral modification continued after the first year of the program.

#### Verification Activities

In addition to the other restrictive measures, the forty-eight hour waiting period in the dispensing of amphetamine and methaqualone prescriptions also was of major importance in the Duval County program. One reason for providing a "cooling off" period was to afford the pharmacist an opportunity to confirm the prescription's validity. One of the pieces of information retrieved during the prescription review was whether a notation of the pharmacists' verification activities was present. For the purpose of this study, a verification activity is defined as follows:

A pharmacist-initiated activity which verifies or substantiates the validity of a prescription with the prescriber.

It should be noted, however, that under the guidelines of the voluntary program, pharmacists were not required to make any notation when a verification activity was performed.

Table 9 presents the tabulation of verification activities by year for both Duval County and Alachua County. Only 335 prescriptions of a total sample of 14,730 prescriptions (2.3 percent) for the three-year period bore notations of verification by a pharmacist. However, there was a significant increase<sup>14</sup> in such activities in Duval County after the initiation of the program, while in the control county, a decrease was observed.

In the experimental county, 270 (90 percent) of the verifications pertained to amphetamine and methaqualone prescriptions, as compared to only sixteen (46 percent) in the control county. These activities remained relatively constant for 1978 and 1979 in Duval County. The figures indicate that the Duval County program had a significant impact on the pharmacists' verification activities.

To summarize, one of the purposes of the Duval County program was to decrease the potential for the forgery of prescriptions for amphetamines and methaqualone. In order to accomplish this purpose, a forty-eight hour moratorium was established to encourage the pharmacists to corroborate the validity of the prescriptions with the prescriber. In the experimental county, there was a significant increase in such activity, while in the control county, there was a decrease. Duval County showed an increase in verification activities of 93.6 percent after the program's inception, while Alachua County showed a 36.8 percent decrease.

The large increase in the verification activities in Duval County after the program began, when taken in conjunction with the decrease observed in the control county, leads to the following conclusion:

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<sup>14</sup><sub>p</sub> < .001



TABLE 9

## Verification Activities by Year for Experimental and Control Counties

Number of Pharmacist-Initiated Verification Activities		
Year	Duval County	Alachua County
1977	26 (0.4%)	19 (1.8%)
1978	143 (5.0%)	12 (1.4%)
1979	131 (5.1%)	4 (0.5%)

The Duval County program was successful in heightening the pharmacists' awareness of the potential for prescription forgeries and subsequently, in increasing his verification activities.

### Participation Level

The last part of the evaluation of the program's outcome is an examination of the program's level of coverage (i.e., the number of pharmacists and physicians who participated). The number was obtained by asking the respondents, via interviews and questionnaires, if they participated in the Duval County program. Table 10 presents the participation status and dates for the sampled pharmacies. Twenty-two (73.3 percent) of the pharmacies in the sample participated in the Duval County program. This compares very favorably with the results obtained for the population during the telephone interviews, where 73.1 percent of the pharmacies indicated that they had participated in the program to some degree (see Table 3).

The prescription audits indicated no significant differences between the pharmacies which had participated in the voluntary program and those which had not. Both groups showed a substantial decline in the number of prescriptions for amphetamines and methaqualone.

The physicians' participation level will be discussed in the next chapter under Physicians' Responses section.

In summary, the participation level for pharmacies was seventy-three percent. However, there was no significant difference in the percentages of decreases in prescription levels for amphetamines and methaqualone between pharmacies of different participatory status. These decreases indicate that there was a sufficient number of physicians and pharmacists

TABLE 10  
Participatory Dates for Sampled Pharmacies\*

Dates of Participation	Number	Percent
December 1977 to end	19	63
January 1978 to end	1	3
December 1977 to June 1979**	1	3
Did not participate	2	7
Did not respond	7	23

\*Percents may not total 100 due to rounding.

\*\*This pharmacy closed on June 16, 1979. The records were transferred to another store at that time. The data from the other store was utilized for the remainder of 1979.

NOTE: The Duval County program officially began on December 1, 1977.

participating in the Duval County program to bring about the successful outcome that has been demonstrated by these results.

### Summary of the Prescription Review Results

The Duval County program had several goals, the most important of which was to impede accessibility of amphetamine and methaqualone drug products in legitimate channels. Two secondary goals which have been identified for the program are: (1) to effect a decrease in the incidence of forged prescriptions for the drugs, and (2) to effect a decrease in the incidence of drug-related robberies. A prescription review was employed, which examined the two drugs, amphetamine and methaqualone, over a three-year period of time beginning one year prior to the program's initiation. Also included within the prescription review were two amphetamine-like drug products, phenmetrazine and methylphenidate, which were subject to similar federal and state controls but were not included within the scope of the Duval County program. Additionally, data for the four drugs were contemporaneously gathered in the control county in order to control for other historical occurrences (with the exception of the Duval County program). The prescription review was designed to gather other data regarding quantities prescribed and the incidence of verification activities.

The data obtained from the prescription review provided a basis for examining the outcomes of the Duval County program as measured by the degree of successfulness of the program in fulfilling its goals.

Attainment of the primary goal was measured directly through the use of the operational variables, Amphetamine, Methaqualone, Methylphenidate and Phenmetrazine Prescriptions each as a Percent of Schedule II prescriptions and their annual per pharmacy mean volume. The results were

in accord. The Duval County program was successful in decreasing the availability of amphetamines and methaqualone.

Attainment of the secondary goals was measured by using different operational variables. The first goal, to effect a decrease in the incidence of forged prescriptions, required the use of verification activity as a measure of its attainment. It was assumed that without a validity check by the pharmacist with the prescriber, forgery detection would be difficult and presumptuous. A significant increase in such activity was noted after the Duval County program began. This highly publicized activity could be expected to discourage the presentation of forged prescriptions. The next chapter details the physicians' perspectives regarding forged prescriptions.

The second goal, to effect a decrease in the incidence of drug-related burglaries and robberies, was more difficult to document. Physicians were requested to prescribe amphetamines and methaqualone in stock-size packages in order to reduce the inventory of these items and thereby lessen the incentives for theft. The stock-size package prescribing activity showed a dramatic increase after the program began. The final chapter details the pharmacists' perceptions regarding the incidence of robberies.

All of the positive actions described in this study exhibit the high degree of success which the Duval County program had attained in fulfilling its mission. The outcomes for 1979 remained consistent with those for 1978. The sustained positive results indicate that the voluntary program exceeded its goals, by achieving a permanent change in the prescribing and dispensing behaviors of the pharmacists and physicians in Duval County.

The final part of the outcome's examination of the Duval County program involves an evaluation of the coverage level. The program was wholly voluntary in nature. Nevertheless, the results showed that seventy-three percent of Duval County pharmacies participated in the program to some degree.

The literature reveals a wide range of compliance with the goals of various programs. The range extends from 13.0 percent [78] to 93.6 percent [79]. One of the major factors which accounts for the disparities in levels of compliance is the process whereby the program is to be implemented [62:1]. The participation level of the voluntary program (73 percent) compares favorably with the upper range for other programs. The implementation process of the Duval County program is detailed in the final chapter.

The next chapter discusses the attitudes of the pharmacists and physicians toward the Duval County program.

## CHAPTER V

### PRACTITIONERS' ATTITUDES AND KNOWLEDGE OF THE DUVAL COUNTY PROGRAM

The second focus of this evaluation is an examination of the participants' attitudes and actions in implementing the goals of the program. This chapter examines that aspect.

One objective of this study is the collection of descriptive information concerning the pharmacists' and physicians' attitudes toward the Duval County program. Other objectives include the elicitation of knowledge as measured by accuracy and degree of precision, possessed by pharmacists and physicians regarding both the Duval County program and the Florida amphetamine law, their attitudes toward amphetamine usage, and the collection of descriptive information concerning factors which influence the participatory status of the pharmacies. Attitudes and knowledge are considered by most social scientists to be of extreme importance to the extent that they may characterize behavior in regard to the actions taken in implementing policy decisions [62:90].

The sample of pharmacists is not a random one, but rather it represents the pharmacists who are associated with the pharmacies involved in this study. The population of physicians comprises the osteopathic and allopathic physicians who were identified as potential amphetamine or methaqualone prescribers and who were practicing in Duval County in 1977 and 1979. The entire population (396) was sampled.

This chapter is divided into three sections:

- (1) pharmacists' responses;
- (2) physicians' responses; and
- (3) a comparison of pharmacists' and physicians' responses.

### Pharmacists' Responses

#### Respondent Characteristics

Table 11 describes characteristics of the pharmacist respondents. Twenty-five (86.2 percent) were male. Most (79 percent) had been practicing pharmacy for at least six years. Eighty-three percent of the pharmacists surveyed held memberships in at least one professional association, 52 percent in two, and 41 percent in three.

When asked how they perceived the Duval County program for success in decreasing amphetamine availability, 65 percent of the respondents replied that they felt that the program had succeeded, 14 percent felt that it had failed, and 21 percent did not respond to the question (see Table 12). These results compare favorably with the results obtained from the telephone interviews of the entire population of Duval County pharmacists, in which 54 percent of the respondents felt the program had succeeded in decreasing amphetamine availability and eight percent felt the program had failed.

Since no statistical evidence was found of a relationship between the gathered characteristics of gender, years in practice and professional association membership and the results obtained from the pharmacists' questionnaire, presentation of demographic information was limited to descriptive detail of the sample and the population.<sup>15</sup>

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<sup>15</sup>Unless further noted, all references to findings in this chapter of statistical significance are based on the Chi Square ( $\chi^2$ ) test.



TABLE 11  
 Characteristics of Pharmacist Respondents

		<u>Gender</u>			
		<u>Male</u>	<u>Female</u>		
n		25	4		
%		(86.2%)	(13.8%)		
		<u>Years in Practice</u>			
		<u>0 - 5</u>	<u>6 - 15</u>	<u>over 15</u>	<u>Did Not Respond</u>
n		6	5	18	0
%		(20.7%)	(17.2%)	(62.1%)	( 0%)
		<u>Professional Affiliations</u>			
		<u>American Pharmaceutical Association</u>			
		<u>Yes</u>	<u>No</u>	<u>Did Not Respond</u>	
n		12	15	2	
%		(41.4%)	(51.7%)	( 6.9%)	
		<u>Florida Pharmacy Association</u>			
		<u>Yes</u>	<u>No</u>	<u>Did Not Respond</u>	
n		15	12	2	
%		(51.7%)	(41.4%)	( 6.9%)	
		<u>Duval County Pharmacy Association</u>			
		<u>Yes</u>	<u>No</u>	<u>Did Not Respond</u>	
n		24	4	1	
%		(82.3%)	(13.8%)	( 3.4%)	

TABLE 12

## Pharmacists' Opinions on the Successfulness of the Duval County Program

	Succeeded	Failed	Unsure	No Response	Total
Population*	56 (54%)	8 ( 8%)	3 ( 3%)	37 (35%)	104 (100%)
Sample**	19 (65%)	4 (14%)	0 ( 0%)	6 (21%)	29 (100%)

\*Obtained from telephone interview.

\*\*Obtained from pharmacists' questionnaire.

In summary, it was found that the typical respondent was a male, who had been in practice at least six years. He was a member of at least one professional association and believed that the Duval County program had succeeded in decreasing amphetamine availability.

#### Pharmacists' Attitudes Toward the Duval County Program

A Likert-type instrument was used to evaluate pharmacists' attitudes toward the Duval County program. Pharmacists were asked to indicate the extent to which they agreed or disagreed with statements concerning the Duval County program. Table 13 shows that most pharmacists believed the program had succeeded and that it should be expanded to a state-wide level. The respondents were evenly divided in their opinions as to whether the program should be made mandatory and whether they believed that most pharmacists were limiting participation in the program to only those persons not considered to be regular customers. There were no provisions in the program for excluding regular patrons of an establishment.

Table 14 presents the pharmacist respondents' perceptions concerning their customers' attitudes toward the Duval County program. Two statements concerned the customers' willingness to accept the delay period in obtaining amphetamine or methaqualone prescriptions. Customers had the opportunity to find a non-participating pharmacy in Duval County or to go outside Duval County where the voluntary program was not in effect. There was a slight disagreement with the statements that the delay has caused numerous customers to go elsewhere and that a significant number of patients had crossed county lines to get their amphetamine prescriptions filled as a result of the program, and slight agreement that most customers accepted the program as a necessary means of controlling drug

TABLE 13

## Pharmacists' Attitudes Toward the Duval County Program\*

	Strongly Agree	1	2	3	4	5	Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
The Jacksonville program has been succeeding in curbing amphetamine misuse.	15 (52%)	3 (10%)	9 (31%)	1 (3%)	1 (3%)	1	1	1	n = 29	1.97	0.21
Most pharmacists that participate do so only for their non-regular customers.**	5 (17%)	7 (24%)	9 (31%)	3 (10%)	4 (14%)	3	3	n = 28		2.62	0.27
The Duval County experiment should be expanded to a state-wide level.**	17 (59%)	2 (7%)	3 (10%)	3 (10%)	3 (10%)	3	3	1	1	1.96	0.28
The Duval County program should be made mandatory.**	8 (28%)	1 (3%)	6 (21%)	2 (7%)	11 (38%)	5	3	n = 28		3.07	0.32

\*Percents may not total 100 due to rounding.

\*\*One respondent (3%) did not respond.

TABLE 14

Pharmacists' Perception of Their Customers' Attitudes About the Program\*

	Strongly Agree					Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
	1	2	3	4	5					
The delay in dispensing has caused numerous customers to go elsewhere.	3 (10%)	3 (10%)	1 (3%)	12 (41%)	10 (35%)		4	4	3.86	0.24
Generally, most customers have accepted this project as a necessary way to control drug abuse.**	6 (21%)	10 (35%)	9 (31%)	1 (3%)	2 (7%)		2	2	2.14	0.21
A significant number of patients are going across county lines to get their amphetamine prescriptions filled.***	0 (0%)	6 (21%)	6 (21%)	2 (7%)	13 (44%)		5	4	3.38	0.31
								n = 27		

\*Percents may not total 100 due to rounding.

\*\*One respondent (3%) did not respond.

\*\*\*Two respondents (7%) did not respond.

abuse. In general, the pharmacists believed that most customers accepted the program and its concomitant delays.

The pharmacists' perception of physician responses to the program appears in Table 15. There is strong agreement with the statement that local physicians have accepted the program, strong disagreement with the statement that physicians have continued to over-prescribe amphetamines and methaqualones and strong disagreement that physicians have significantly increased their dispensing of amphetamines as a result of the Duval County program. In general, the pharmacists believed that most physicians had accepted the program and had decreased their prescribing of the included drugs.

Table 16 presents the pharmacists' perceptions concerning various types of pressure applied to other pharmacists to induce them to participate in the voluntary program. There is slight disagreement with all statements about the types of pressure applied to encourage participation in the program. Pressure from fellow pharmacists, pressure from the Duval County Pharmacy Association, public pressure and outright coercion all received similar negative responses. In general, the pharmacists believed that there was very little pressure applied, either from peer groups or from outside groups, to encourage participation in the voluntary program.

Four additional statements were included in this section of the questionnaire. The first two statements concerned amphetamine misuse: the pharmacists strongly agreed with both statements that the anti-obesity indication for amphetamines should not be a use approved by the FDA; and, the new Florida amphetamine law will help curb their misuse. These results appear in Table 17. The second two statements concern general drug

TABLE 15

Pharmacists' Perception of Physician Responses to the Program\*

	Strongly Agree	1	2	3	4	5	Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
In general, local doctors have accepted the program.	12 (41%)	9 (31%)	8 (28%)	0 (0%)	0 (0%)	0 (0%)	1	n = 29	2	1.82	0.15
In general, doctors are continuing to over prescribe these drugs.	3 (10%)	1 (3%)	1 (3%)	10 (35%)	14 (48%)	5	4	n = 29	4	4.07	0.24
There has been a significant increase in physician dispensing of amphetamines as a result of this program. **	2 (7%)	0 (0%)	1 (3%)	3 (10%)	21 (73%)	5	5	n = 27	5	4.38	0.26

\*Percents may not total 100 due to rounding.

\*\*Two respondents (7%) did not respond.

TABLE 16

## Pharmacists' Perceptions Concerning Pressure Applied to Participate in the Duval County Program\*

	Strongly Agree	1	2	3	4	5	Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
In general, most local pharmacists were coerced into participating in the program.**	1 (3%)	7 (24%)	2 (7%)	3 (10%)	15 (52%)	5	n = 28	5	5	3.72	0.28
Pressure from fellow pharmacists was the reason many pharmacies agreed to participate in the program.	1 (3%)	6 (20%)	2 (7%)	9 (31%)	11 (38%)	5	n = 29	5	4	3.66	0.27
Public pressure was the reason many pharmacies agreed to participate in the program.**	1 (3%)	5 (17%)	4 (14%)	8 (28%)	10 (35%)	5	n = 28	5	4	3.48	0.29
The Duval County Pharmacy Association applied pressure to get most of the pharmacists to participate in the program.**	1 (3%)	1 (3%)	8 (28%)	4 (14%)	14 (48%)	5	n = 28	5	5	3.79	0.28

\*Percents may not total 100 due to rounding.

\*\*One respondent (3%) did not respond to this question.



TABLE 17  
Pharmacists' Attitudes Regarding Issues Involving Amphetamine Misuse\*

	Strongly Agree	1	2	3	4	5	Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
The anti-obesity indication should <u>not</u> be an FDA approved use of amphetamine drugs.**	18 (62%)	3 (10%)	5 (17%)	0 (0%)	1 (3%)	1	1	1	n = 27	1.76	0.24
The new state law banning the use of amphetamines for weight control will help curb their misuse.	20 (70%)	3 (10%)	3 (10%)	2 (7%)	1 (3%)	1	1	1	n = 29	1.62	0.21

\*Percents may not total 100 due to rounding.

\*\*Two respondents (7%) did not respond.

abuse issues and appear in Table 18. The mean rating showed no discernable consensus regarding the rechanneling of prescription drugs into a source of illicit "street" drugs. But there was slight disagreement with the statement that state and federal attempts to curb drug abuse have been successful in decreasing the problem.

To summarize, pharmacists generally favored the concept of the Duval County program, they felt that it was successful in decreasing amphetamine availability, and felt that it should be expanded to a state-wide level. They also perceived that physicians accepted the program and thereby reduced their prescribing of amphetamines and methaqualones. They felt that customers accepted the program as a necessary part of drug abuse control. Pharmacists tended to disagree with statements concerning the application of pressure on them to encourage their participation in the experiment. They were highly supportive of the Florida amphetamine law and FDA attempts to remove the weight-reduction indication from amphetamine products. They were slightly negative in their assessment of prior state and federal efforts to control drug abuse.

#### Pharmacists' Knowledge of the Duval County Program

The pharmacists' questionnaire contained eleven questions relating to their knowledge about the specifics of the Duval County program. Six of these questions related to the specific drug products that were included within the scope of the program and five questions related to specific activities. Each pharmacist selected the correct answers to the best of his knowledge. Table 19 presents the pharmacists' over-all scores and Table 20 presents their responses to questions regarding the specifics of the voluntary program. The pharmacists' mean score

TABLE 18  
Pharmacists' Attitudes Regarding Issues Involving General Drug Abuse\*

	Strongly Agree					Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
	1	2	3	4	5					
The source of most illicit "street" drugs is the resale of drugs obtained through a prescription.	2 ( 7%)	6 (21%)	8 (28%)	7 (24%)	6 (21%)	3	3	n = 29	3.31	0.22
State and federal attempts to curb drug abuse have been very successful in decreasing the problem.	1 ( 3%)	1 ( 3%)	7 (24%)	10 (35%)	10 (35%)	4	4	n = 29	3.97	0.19

\*Percents may not total 100 due to rounding.

TABLE 19  
Pharmacists' Knowledge of the Duval County Program and Florida Amphetamine Law

Index	Duval County Program (n = 29)			
	$\frac{\text{Number Correct}}{\text{Possible Number Correct}}$	Aggregate Score (Percent)	Individual Mean Score (Percent)	Standard Error
Covered Drugs (Question #6)*	122/174	70.1	70.1	4.1
Covered Activities (Question #6)	109/145	75.2	77.0	3.3
Accuracy Rating (All Questions)	231/319	72.4	72.4	2.8
Perfect Responses (All Questions)	1/29	3.4	----	---
	Florida Amphetamine Law (n = 29)			
	$\frac{\text{Number Correct}}{\text{Possible Number Correct}}$	Aggregate Score (Percent)	Individual Mean Score (Percent)	Standard Error
Accuracy Rating (All Questions)	361/435	83.0	83.9	1.8
Precision (Question #3)	23/29	79.3	----	---
Practice Limitation (Questions #3, 4)	58/232	25.0	25.0	3.4
Malpractice (Questions #3, 4)	16/203	7.9	9.8	3.7
Perfect Responses (All Questions)	2/29	6.7	----	---

\*See Appendix II

TABLE 20  
Pharmacists' Answers on the Specifics of the Duval County Program

Covered Drugs	Number of Correct Responses	Number of Incorrect Responses	Percent Correct
Amphetamines*	26	3	89.7
Methaqualone*	26	3	89.7
Dilaudid**	11	18	37.9
Percodan**	7	22	24.1
Phenmetrazine**	8	21	27.6
All C-II drugs**	22	7	75.9

Covered Activities	Number of Correct Responses	Number of Incorrect Responses	Percent Correct
24-hour delay**	22	7	75.9
48-hour delay*	20	9	69.0
Stock-size packaging*	11	18	37.9
Jacksonville physicians**	28	1	96.6
Non-regular patrons**	28	1	96.6

\*This item was included within the scope of the Duval County program.

\*\*This item was not included within the scope of the Duval County program.

involving the drug products included in the program is listed following the index, Covered Drugs. The relatively low mean score of 70.1 percent was due primarily to their misconception that other drug products, in addition to amphetamines and methaqualone, were included in the program. Twenty-six (90 percent) correctly identified amphetamine and methaqualone as included drugs. The index, Covered Activities, was used to indicate the pharmacists' mean score involving the activities that were part of the Duval County program. As above, the comparatively low mean score (77 percent) was due mainly to the pharmacists' misconception that more activities were included in the program than actually were.

The two indices, Covered Drugs and Covered Activities, were combined to create a new index, Accuracy Rating, which indicates the percentage of correct responses for the average pharmacist in accordance with the Duval County program. The pharmacists' mean score was 72.4 percent, but as suggested above, this was mainly the result of the broad interpretation which they had given to the program's scope. The rating for identifying included drugs was greater than 90 percent. Therefore, these scores can be interpreted as meaning the average pharmacist's knowledge of the Duval County program for included drugs is extremely high and the information dissemination process worked well in familiarizing them with the facts. However, the belief by 73.4 percent of the pharmacists that several non-included drugs were indeed included, although not detrimental to the aims of the program, poses questions for future endeavors into voluntary drug control. This will be discussed in the next section. Only one pharmacist (3.4 percent) attained a score of 100 percent.

### Pharmacists' Knowledge of the Florida Amphetamine Law

Pharmacists were also asked 16 questions which examined their knowledge of the specifics of the Florida amphetamine law. This was done in order to perform a descriptive comparison of the practitioners' knowledge of a voluntary program (Duval County program) to their knowledge of a state mandated program (Florida amphetamine law). Table 19 presents the comparison of the overall ratings the average pharmacist received on the questions concerning both programs. Table 21 shows the responses to questions regarding the specifics of the mandated program. The index, Precision, indicates the percentage of respondents who were able to differentiate methylphenidate (Ritalin®) from the list of included drugs. Methylphenidate is not regulated by the Florida amphetamine law, but initially there was a debate about its status. Twenty-three pharmacists were able to make this differentiation, therefore, 80 percent of the pharmacists in the study are precise in their knowledge of that aspect of the Florida amphetamine law.

The index, Practice Limitation, describes how many of the pharmacists' responses indicated that they thought legal restrictions existed when, in fact, they did not, thereby unnecessarily limiting their practice. Twenty-five percent of the pharmacists' responses belonged to this category. This deviation from the requirements of the law was not, in general, considered harmful to the public's welfare since it curbed the availability of other stimulants. However, the index, Malpractice, indicates the percent of responses by pharmacists which did not correctly identify restrictions of the Florida amphetamine law. This could lead to inappropriate dispensing behavior if they improperly dispensed prescriptions in reliance on their inadequate knowledge of the law. Only eight percent of

TABLE 21

## Pharmacists' Answers on the Specifics of the Florida Amphetamine Law

Item	Number of Correct Responses	Number of Incorrect Responses	Percent Correct
Amphetamine*	27	2	93.1
Phenmetrazine*	22	7	75.9
Methylphenidate**	23	6	79.3
Benzphetamine**	25	4	86.2
Phentermine**	29	0	100.0
Phendimetrazine**	29	0	100.0
All sympathomimetic amines**	22	7	75.9
Narcolepsy*	27	2	93.1
Hyperkinesis*	26	3	89.7
Anorexia**	29	0	100.0
Depression*	8	21	27.6
Obesity**	29	0	100.0
Any clinical investigations**	24	5	82.8
Weight loss programs**	27	2	93.1
Board approved investigations*	8	21	27.6
Stimulant**	29	0	100.0

\*This item is included as part of the Florida amphetamine law.

\*\*This item is not included as part of the Florida amphetamine law.



the pharmacists' responses fell into this category. This low score may be interpreted as meaning the pharmacists' knowledge of the specifics of the laws in important areas is adequate and serves the public welfare.

The two indices, Practice Limitation and Malpractice, were combined to create another index, Accuracy Rating, which indicates the percent of correct responses of the average pharmacist in accordance with the Florida amphetamine law. The pharmacists' mean score was 83.9 percent, the result mainly of the practice limiting aspects rather than the potential malpractice ones. Two pharmacists (6.7 percent) attained a score of 100 percent.

### Physicians' Responses

#### Respondent Characteristics

The characteristics of the physician respondents are described in Table 22. The vast majority (83 percent) were male. One hundred and eleven (77 percent) were between 35 and 65 years old. Seventy-seven percent were members of at least one professional association and 53 percent were members of two.

Table 23 presents physician responses by specialty and the response rates by degree type. Four specialties, family practice, internal medicine, gynecology and surgery, accounted for more than 60 percent of the responses. Allopathic physicians (M.D.) represented 91 percent of the total responses and osteopathic physicians (D.O.) represented nine percent. The response rate for M.D.'s was 37 percent and for D.O.'s 54 percent. The overall response rate was 38 percent.

There was no statistical evidence of a relationship between the characteristics (gender, age, degree type, professional association

TABLE 22  
Characteristics of Physician Respondents

		<u>Gender</u>		
		<u>Male</u>	<u>Female</u>	<u>Did Not Respond</u>
n	123		4	22
%	(82.6%)		(2.7%)	(14.7%)

		<u>Age</u>				
		<u>less than 35</u>	<u>35-50</u>	<u>51-65</u>	<u>over 65</u>	<u>Did Not Respond</u>
n	6	57	58	6		22
%	(4.0%)	(38.3%)	(38.9%)	(4.0%)		(14.7%)

		<u>Degree Type</u>	
		<u>M.D.</u>	<u>D.O.</u>
n	136		13
%	(91.3%)		(8.7%)

		<u>Professional Affiliations</u>		
		<u>American Medical Association</u>		
		<u>Yes</u>	<u>No</u>	<u>Did Not Respond</u>
n	79		46	24
%	(53.0%)		(30.9%)	(16.1%)

		<u>Duval County Medical Society</u>		
		<u>Yes</u>	<u>No</u>	<u>Did Not Respond</u>
n	115		12	22
%	(77.2%)		(8.1%)	(14.7%)

TABLE 23

## Physicians' Responses by Degree Type and Specialty

Practitioner's Degree	Number Sent	Number of Responses	Percent
D.O.	24	13	54.2
M.D.	372	136	36.6
Total	396	149	37.6

Practitioner's Specialty	Number of Responses	Percent
Family Practice	30	20.1
General Practice	5	3.4
Internal Medicine	21	14.1
Diet/Weight Control	1	0.7
Obstetrics/Gynecology	22	14.8
Pediatrics	11	7.4
Psychiatry	4	2.7
Surgery	17	11.4
Neurology	4	2.7
Cardiology	2	1.3
Gastroenterology	2	1.3
Industrial	1	0.7
Other (Unspecified)	3	2.0
Did Not Answer	26	17.4
Total	149	100.0

membership and specialty) and the results obtained from the physicians' questionnaire. Therefore, the demographic information was utilized to describe the sample and the population.

In summary, it was found that the typical physician respondent was a male who was between 35 and 65 years old. He had an M.D. degree and was a member of at least two professional associations.

#### Physicians' Attitudes Toward the Duval County Program

A Likert instrument which asked physicians to indicate the extent to which they agreed or disagreed with statements relating to the Duval County program was used. Table 24 sets forth physicians' ratings of statements concerning the program itself. Physicians generally indicated slight agreement with the statements that the program was successful in decreasing amphetamine misuse, that the concept of the program was good, and that the program should be expanded to a state-wide level. There was no discernable consensus regarding the statement that the program be made mandatory. In general, physicians believed in the concept of the program and that the program was successful in decreasing amphetamine misuse in Jacksonville.

Four additional questions were included in this section of the questionnaire. Two statements concerned amphetamine misuse (Table 25). Physicians slightly agreed that the Florida amphetamine law will aid in curbing amphetamine misuse and they strongly agreed that the anti-obesity indication should not be a FDA-approved usage of amphetamines. Table 26 indicates the physicians' attitudes toward the other two questions involving general drug abuse. The mean rating showed that physicians were evenly divided in their opinion in regard to the rechanneling of

TABLE 24

## Physicians' Attitudes Toward the Duval County Program\*

	Strongly Agree					Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
	1	2	3	4	5					
The Duval County voluntary moratorium has been effective in decreasing amphetamine misuse or abuse. **	58 (39%)	25 (17%)	12 ( 8%)	3 ( 2%)	2 ( 1%)	1	1	n = 100	1.66	0.09
The Duval County voluntary moratorium is in general a good concept. ***	74 (50%)	21 (14%)	5 ( 3%)	2 ( 1%)	5 ( 3%)	1	1	n = 107	1.53	0.10
The voluntary moratorium should be made mandatory. ****	35 (23%)	18 (12%)	18 (12%)	7 ( 5%)	24 (16%)	1	2	n = 102	2.68	0.16
The voluntary moratorium should be expanded to a state-wide level. *****	70 (47%)	19 (13%)	7 ( 5%)	4 ( 3%)	5 ( 3%)	1	1	n = 105	1.62	0.11

\*Percents may not total 100 due to rounding.

\*\*Forty-nine respondents (33%) did not respond.

\*\*\*Forty-two respondents (28%) did not respond.

\*\*\*\*Forty-seven respondents (32%) did not respond.

\*\*\*\*\*Forty-four respondents (29%) did not respond.

TABLE 25  
Physicians' Attitudes Regarding Issues Involving Amphetamine Misuse\*

	Strongly Agree					Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
	1	2	3	4	5					
The new state law banning the use of amphetamines for weight control will help curb their misuse.**	43 (29%)	16 (11%)	24 (16%)	13 (9%)	9 (5%)	1	n = 105	2	2.32	0.13
The anti-obesity indication should <u>not</u> be a FDA approved use of amphetamine drugs.***	57 (38%)	17 (11%)	11 (7%)	4 (3%)	8 (5%)	1	n = 97	1	1.86	0.13

\*Percents may not total 100 due to rounding.

\*\*Forty-four respondents (30%) did not respond.

\*\*\*Fifty-two respondents (35%) did not respond.

TABLE 26  
Physicians' Attitudes Regarding Issues Involving General Drug Abuse\*

	Strongly Agree	1	2	3	4	5	Strongly Disagree	Mode Rating	Median Rating	Mean Rating	Standard Error
The source of most illicit "street" drugs is the resale of drugs obtained through a prescription.**	13 ( 9%)	22 (15%)	29 (19%)	26 (17%)	30 (20%)	5	5	n = 120	3	3.32	0.12
State and federal attempts to curb drug abuse have been very successful in decreasing the problem.***	2 ( 1%)	7 ( 5%)	24 (16%)	36 (24%)	53 (36%)	5	5	n = 122	4	4.07	0.09

\*Percents may not total 100 due to rounding.

\*\*Twenty-nine respondents (19%) did not respond.

\*\*\*Twenty-seven respondents (18%) did not respond.

prescription drugs into a source of "street" drugs. There was strong disagreement with the statement that state and federal attempts have been successful in decreasing the drug abuse problem.

Table 27 shows the physicians' perceptions of their patients' difficulties in having their amphetamine prescriptions filled. Only twelve physicians (8 percent) responded that any of their patients had experienced problems. Many physicians (42 percent) replied that they did not prescribe amphetamines. Twenty-four percent indicated that their patients had not reported any problems to them.

The physicians' perceptions of pharmacist responses to the program are presented in Table 28. Seventy (47 percent) had specific knowledge that certain pharmacies were participating in the voluntary program and twenty-eight percent were not aware of any pharmacies that participated. Table 29 indicates physicians' perceptions of the verification activities of pharmacists. Only seventeen (11 percent) indicated that had been contacted about the validity of an amphetamine prescription, a result of which seventy-one percent of those contacted attributed to the 48-hour "cooling-off" period. Twelve of the seventeen who had been contacted (71 percent) indicated that at least one forgery had been detected as a result of these contacts and ten of the seventeen (59 percent) indicated that between two and five forgeries had been detected through such contacts.

In Table 30, the physicians' notions as to overall physician responses to the program are presented. Only six (4 percent) thought their peers had increased the dispensing of amphetamines to patients. Twenty percent of the physicians indicated that they had decreased their prescribing of amphetamines and none indicated that they had increased it.



TABLE 27

Physicians' Perceptions of Their Patients' Difficulty  
in Having Their Amphetamine Prescriptions Filled

Are you aware of any of your patients having a difficult time having their prescriptions for amphetamines filled?				
<u>Yes</u> <u>(to a large extent)</u>	<u>Yes</u> <u>(to a small extent)</u>	<u>No</u>	<u>Does Not Apply*</u>	
			<u>Did Not Respond</u>	
6 (4.0%)	6 (4.0%)	35 (23.5%)	63 (42.3%)	39 (26.2%)

\*Does not apply, do not prescribe amphetamines.

TABLE 28

Physicians' Perceptions of Pharmacists' Responses to the Program

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Are you aware of any pharmacies  
that are participating in this moratorium?

<u>Yes</u>	<u>No</u>	<u>Did Not Respond</u>
70	41	38
(47.0%)	(27.5%)	(25.5%)

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TABLE 29

## Physician's Perceptions of Pharmacist Verification of Prescription Validity

Have you ever been contacted about the validity of an amphetamine prescription by a pharmacist?			
<u>Yes</u>	<u>No</u>	<u>Does Not Apply*</u>	<u>Did Not Respond</u>
17 (11.4%)	40 (26.9%)	57 (38.3%)	35 (23.4%)
Do you think it was because of the 48-hour "cooling" period?			
<u>Yes</u>	<u>No</u>		
12 (70.6%)	5 (29.4%)		
Has there been a forged prescription detected as a result of these contacts?			
<u>Yes</u>	<u>No</u>		
12 (70.6%)	5 (29.4%)		
How many times?			
<u>1</u>	<u>2 - 5</u>		<u>over 5</u>
6 (35.3%)	10 (58.8%)		1 (5.9%)

111

\*Does not apply, do not prescribe amphetamines.

TABLE 30  
Physicians' Perceptions of Physician Responses to the Program

Because of the publicity and/or the program, has there been a change in your prescribing of amphetamines?			
<u>Yes (decreased)</u>	<u>Yes (increased)</u>	<u>No</u>	<u>Does Not Apply*</u> <u>Did Not Respond</u>
30 (20.1%)	0 ( 0%)	36 (24.2%)	44 (29.5%) 39 (26.2%)
Do you think there has been an increase in the number of physicians who dispense amphetamines as a result of the program?			
<u>Yes</u>		<u>No</u>	<u>Did Not Respond</u>
6 (4.0%)		88 (59.1%)	55 (36.9%)

\*Does not apply, do not prescribe amphetamines.

To summarize, physicians generally favored the concept of the Duval County program, they felt it was successful in accomplishing its goals, and they felt that it should be expanded to a state-wide level. They expressed no opinion on making the program mandatory or on the rechanneling activities involving the resale of prescription drugs for "street" drug use. They felt strongly that state and federal efforts in combating the problem of drug abuse had failed but they agreed slightly that the Florida amphetamine law would help decrease amphetamine misuse and that the FDA should remove the anti-obesity indication from amphetamine products. Physicians, who prescribed amphetamines, were not aware of their patients experiencing difficulties with getting their prescriptions filled. Most of the respondents were aware of pharmacies that participated in the program and did not think any physicians had increased their dispensing of amphetamines to patients.

#### Physicians' Knowledge of the Duval County Program

The physicians' questionnaire contained nine questions which examined their knowledge about the specifics of the Duval County program. Each physician was asked to select the correct answer to each question to the best of his knowledge. Table 31 presents the physicians' overall scores on these questions about the Duval County program and Table 32 indicates their responses regarding the specifics of the program. The physicians had a mean score of 76.4 percent on the questions relating to the index, Covered Drugs. As with the pharmacists' similar scoring the physicians' score was primarily due to their misbelief that there were other drug products included within the program's scope in addition to amphetamines and methaqualone. Ninety-five percent of the physicians correctly

TABLE 31  
Physicians' Knowledge of the Duval County Program and Florida Amphetamine Law

Index	Duval County Program (n = 121)		Individual Mean Score (Percent)	Standard Error
	Number Correct	Aggregate Score (Percent)		
	Possible	Number Correct		
Covered Drugs (Question #5)*	555/726	76.4	76.4	1.9
Covered Activities (Question #5)	246/363	67.8	69.6	1.4
Accuracy Rating (All Questions)	801/1089	73.6	73.0	1.7
Perfect Responses (All Questions)	4/121	3.3	----	---
Florida Amphetamine Law (n = 83)				
Accuracy Rating (All Questions)	967/1245	77.7	78.6	1.7
Precision (Question #2)	31/83	37.3	----	---
Practice Limitation (Questions #2, 3)	199/664	30.0	30.0	2.9
Malpractice (Questions #2, 3)	79/581	13.6	16.9	2.4
Perfect Responses (All Questions)	1/83	1.2	----	---

\*See Appendix IV

TABLE 32

## Physicians' Answers on the Specifics of the Duval County Program

Covered Drugs	Number of Correct Responses	Number of Incorrect Responses	Percent Correct
Amphetamines*	115	6	95.0
Methaqualone*	93	28	76.9
Dilaudid**	81	40	66.9
Percodan**	91	30	75.2
Phenmetrazine**	82	39	67.8
All C-II drugs**	93	28	76.9

Covered Activities	Number of Correct Responses	Number of Incorrect Responses	Percent Correct
Stock-size packaging*	17	104	14.1
Non-regular patrons**	121	0	100.0
Jacksonville physicians*	108	13	89.3

\*This item was included within the scope of the Duval County program.

\*\*This item was not included within the scope of the Duval County program.

identified amphetamine as being an included drug and seventy-seven percent correctly identified methaqualone. The index, Covered Activities, was used to denote the physicians' mean score on the questions involving the activities that were part of the voluntary program. The physicians' somewhat low mean score of 69.6 percent was, again primarily due to their misconceptions regarding the scope of the program.

A third index, Accuracy Rating, was created by combining the scores of the above two indices, Covered Drugs and Covered Activities. The physicians' mean score was seventy-three percent. These three scores can be interpreted as meaning that the physicians' knowledge of the specifics of the Duval County program for included drugs is much higher than for non-included drugs. This shows that the physicians were well informed about the important included drugs and activities and that they were less informed about what was not included. Four physicians (3.3 percent) received a score of 100 percent.

#### Physicians' Knowledge of the Florida Amphetamine Law

Physicians were asked 16 questions relating to their knowledge of the specifics of the Florida amphetamine law. Table 31 presents a comparison of the overall scores the physicians attained on the questions concerning the Duval County program and Florida amphetamine law. Table 33 details their answers to questions regarding the specifics of the law. The index, Precision, indicates the percentage of respondents who correctly identified methylphenidate as not being regulated under this law. Only 37 percent of the physicians were precise in this knowledge. This may be because of the initial uncertainty of its status under the law.



TABLE 33  
Physicians' Answers on the Specifics of the Florida Amphetamine Law

Item	Number of Correct Responses	Number of Incorrect Responses	Percent Correct
Amphetamine*	80	3	96.4
Phenmetrazine*	44	39	53.0
Methylphenidate**	52	31	62.7
Benzphetamine**	50	33	39.8
Phentermine**	67	16	19.3
Phendimetrazine**	72	11	86.7
All sympathomimetic amines**	68	15	81.9
Narcolepsy*	80	3	96.4
Hyperkinesia*	65	18	78.3
Anorexia**	82	1	98.8
Depression*	31	52	37.3
Obesity**	81	2	97.6
Any clinical investigations**	57	26	68.7
Weight loss programs**	76	7	91.6
Board approved investigations*	32	51	38.5
Stimulant**	82	1	98.8

\*This item is included as part of the Florida amphetamine law.

\*\*This item is not included as part of the Florida amphetamine law.

The index, Practice Limitation, has been given the same definition for physicians as for pharmacists (i.e., the number of responses indicating that legal restrictions applied when in fact, they did not, thus limiting their practice unnecessarily). Thirty percent of the physician responses were in this category and as with the pharmacists' responses, these deviations from the legal mandate were neither considered harmful nor a problem which needed correction. However, fourteen percent of the physicians' responses belonged in the Malpractice category. The major contributory factor to this high percentage of incorrect answers was the large number of physicians (47 percent) who did not realize that phenmetrazine (Preludin<sup>®</sup>) is regulated by the law and the large number (31 percent) who thought that any clinical investigation is permitted under the act.

The Accuracy Rating index is synthesized from the two indices, Practice Limitation and Malpractice. Seventy-nine percent of the physicians' responses were answered congruent with the Florida amphetamine law. It should be emphasized that a large portion of the physicians (44 percent) did not respond to these questions because they had indicated they were not aware of the law (see Table 34). The low score on the Accuracy Rating and the small percentage of physicians who were aware of the law indicates that the information dissemination process informing physicians of changing legal mandates is in need of improvement. Only one physician (1.2 percent) received a score of 100 percent.

#### Comparison of Pharmacists' and Physicians' Responses

Table 34 presents a comparison of the pharmacists' and physicians' awareness of both the Duval County program and the Florida amphetamine

TABLE 34

Pharmacists' and Physicians' Awareness of the Duval  
County Program and the Florida Amphetamine Law

Are you aware of the Duval County Pharmacy Association's voluntary program that bans the dispensing of amphetamines for 48 hours after the receipt of the prescription?

	Yes	No	Did Not Respond
Physician	122 ( 81.9%)	25 (16.8%)	2 ( 1.3%)
Pharmacist	29 (100%)	0 ( 0%)	0 ( 0%)

Are you aware of the new Florida law concerning the prescribing and dispensing of amphetamines?

	Yes	No	Did Not Respond
Physician	82 ( 55.0%)	65 (43.7%)	2 ( 1.3%)
Pharmacist	29 (100%)	0 ( 0%)	0 ( 0%)

law. All pharmacists indicated that they were aware of both programs. However, there was significant difference<sup>16</sup> between the physicians' awareness of the different programs. One hundred and twenty-two (82 percent) indicated they were aware of the Duval County program and only eighty-two (55 percent) indicated their awareness of the Florida amphetamine law. This difference can be partially attributed to the fact that the physicians had the opportunity to be more involved with the Duval County program through the Duval County Medical Society, and its role in formulating and implementing the voluntary program.

A comparison of the pharmacists' and physicians' ratings for the Likert-type questions that were asked of both practitioners is presented in Table 35. It exhibits very little difference between their ratings. Only the question regarding the potential of the Florida amphetamine law to help curb amphetamine misuse shows any degree of difference, with the pharmacists agreeing slightly more with the statement than did physicians, but even this was not statistically significant. In general, pharmacists and physicians felt that the program was successful and should be expanded to a state-wide level. They also felt that weight-control should not be a FDA-approved use for amphetamines. There was no consensus among the practitioners as to whether the program should be made mandatory and whether rechanneled prescription drugs are a major source of illicit "street" drugs. Both groups felt that federal and state efforts to control the problem of drug abuse have been less than successful.

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<sup>16</sup>A F-test was used here,  $p < 0.001$

TABLE 35

Comparison of Average  
Pharmacist's and Physician's Ratings\*,\*\*

	Strongly Agree			Strongly Disagree	
	1	2	3	4	5
The Duval County Program has succeeded in decreasing amphetamine misuse.		[R] [M]			
The program should be expanded to a state-wide level.		[R] [M]			
The program should be made mandatory.			[R] [M]		
The anti-obesity indication should <u>not</u> be a FDA approved use of amphetamines.		[R] [M]			
The Florida amphetamine law will help curb their abuse		[R] [M]			
The source of most illicit "street" drugs is the resale of drugs obtained through a prescription.			[R] [M]		
State and federal attempts to curb drug abuse have been very successful in decreasing the problem.				[R] [M]	

\*Standard Error is bracketed around each point.

\*\*Pharmacists' responses represented by R.

Physicians' responses represented by M.

Now that the outcomes of the voluntary program and the dispositions of the implementers have been examined, it is possible to arrive at some conclusions regarding the implementation process. The next chapter summarizes the findings of this evaluation, discusses the conclusions the researcher has drawn concerning the implementation of the Duval County program, and presents several areas for potential research by interested investigators.

## CHAPTER VI

### SUMMARY AND CONCLUSIONS

The methodology used to evaluate the implementation process and the outcomes of the Duval County program has been discussed in Chapters III, IV and V. In this final chapter the program's development and implementation processes are discussed and the program's effectiveness and implementation are assessed. Additionally, there is a discussion of the conclusions drawn from this evaluation and also suggestions of areas for future research.

#### Program Development

In early 1977, Hans Tanzler, then mayor of Jacksonville, Florida, after watching an NBC Nightly News television broadcast, became aware of a Kentucky program to limit amphetamine distribution. Shortly thereafter, he contacted the president of the Duval County Pharmacy Association, Cy Kothman, and requested that he investigate the need for a similar program in the area. Mr. Kothman's preliminary investigation revealed that:

- (1) a recent study by area wholesalers showed that Northeast Florida had a higher consumption of amphetamines than the national average; and
- (2) an informal poll taken at a Duval County Pharmacy Association meeting indicated that six physicians had accounted for approximately ninety percent of all the amphetamine prescriptions in town [80].

As a direct result of these revelations a liaison committee (The Joint Committee on Amphetamines) was established by the Duval County Pharmacy Association, the Duval County Medical Society, and the Duval County Osteopathic Society "to further study and implement a program for amphetamine prescription reduction." [81] The Committee released its report on October 15, 1977. The report stated that amphetamine "over-use is clearly evident" [82] in the Jacksonville metropolitan area and recommended a three-point plan for "tackling the problem from the vantage point of its respective physician/pharmacist roles." [82] Specifically, the Committee recommended the following voluntary measures:

- (1) the removal of all amphetamines from pharmacy inventories;
- (2) institution of a 48-hour delay for legitimate prescription filling; and
- (3) the inclusion of methaqualone in the program [82].

The goals of the program as explicitly stated were as follows:

- (1) "to diminish availability of amphetamines obtained through illegal channels; and
- (2) to discourage physician prescribing of amphetamines for obesity." [82]

The following week the three professional associations accepted the recommendations by voting overwhelmingly in favor of instituting a voluntary program to limit amphetamine and methaqualone distribution. The three measures that the Committee had recommended were incorporated within this program along with an additional feature, the prescribing of drugs in stock-size quantities. It was also decided to delay implementation of the program for five weeks in order to provide sufficient time for pharmacies to reduce their inventories of amphetamines and methaqualone and to provide



physicians ample opportunity "to institute substitute therapy for those individuals who had become dependent on these agents." [52]

### Program Implementation

Implementation procedures began immediately following the decision to institute the program. As a first step, detailed information regarding procedures to be followed was mailed to the members of each of the participating professional associations. In addition, a compilation of original package sizes was prepared and made available to all pharmacists and physicians upon request.

Of prime importance to the success of the program was the enthusiastic endorsement by the Jacksonville press which provided complete coverage of all the events leading up to the program's initiation. The editorial departments of the city's two leading newspapers, The Jacksonville Journal and The Florida Times-Union, ran laudatory columns on the voluntary effort by the pharmacists and physicians. The accounts disseminated by the newspapers provided sufficient information to adequately inform Jacksonville citizens about the program and to warn abusers that action was being taken to halt the abuse. The importance of the media's coverage and endorsement of the program cannot be overemphasized. The Jacksonville press was the major vehicle for disseminating information from the pharmacists and the physicians to the public.

The local professional journals also published information. In addition, a letter was sent by the president of the Duval County Medical Society to the presidents of each of the specialty societies. This letter, which detailed the intent of the program, stated that there was no rational basis for the use of amphetamines in the treatment of obesity and pointed out that the program offered an excellent opportunity for peer review.

On November 4, 1977, NBC provided national television coverage on "The Today Show" by spotlighting the Duval County program.

The program went into operation on December 1, 1977 and feature articles again appeared in each newspaper extolling its benefits. Each professional association continued to stress the program's merits throughout the implementation period.

Implementation procedures may be improved and goal attainment may be ensured through the use of follow-up procedures [62:154]. Such procedures were utilized through the following mechanisms:

- (1) Cy Kothman undertook a small-scale evaluation of the program 90 days after the program's initiation. He audited the records of two local wholesalers for amphetamine and methaqualone drug purchases. The data indicated that an 81 percent decrease in amphetamine purchases and a 56 percent decrease in methaqualone purchases had taken place concurrent with the program [52]. These results were presented to the professional associations to reinforce their actions;
- (2) Two follow-up editorials appeared in the local newspapers on February 7, 1977 commending the apparent success of the program [83, 84];
- (3) DEA officials sent letters to the professional associations commending the actions that they were taking in "combatting the drug abuse problem in Jacksonville." [85, 86] Additionally, DEA published a pamphlet on the program based on a feature story which had appeared in The Jacksonville Magazine [42]; and
- (4) The Florida Pharmacy Association overwhelmingly endorsed the program, again reinforcing the actions taken by the pharmacists and physicians [52].

### Program Assessment

In response to the need for a large scale, professional evaluation of the Duval County program, this project was initiated in late 1980. The primary intent of the Duval County program was to impede accessibility of amphetamine and methaqualone drug products in legitimate channels. Two secondary goals have been identified for the program: one, to effect a decrease in the incidence of drug related robberies; and two, to effect a decrease in the incidence of forged prescriptions for the drugs. A prescription review was employed to examine the volume of the two included drug groups, amphetamine and methaqualone dispensed over a three-year period of time beginning one year prior to the program's initiation. Also included within the prescription review were two amphetamine-like drug products, phenmetrazine and methylphenidate, which were subject to similar federal and state controls but were not included within the scope of the Duval County program. Additionally, data for the four drugs were gathered in a control county for the same period of time.

The results lead to several conclusions. First, the Duval County program was successful in decreasing availability of and accessibility to amphetamine and methaqualone drug products. The results showed a 73.3 percent decrease in amphetamine prescriptions and a 67.2 percent decrease in methaqualone prescriptions one year after the program's initiation. The trend continued for the second year.

Second, a positive spillover effect resulted in a 51.7 percent decrease in one of the evaluative control drugs, phenmetrazine, inasmuch as a majority of the pharmacists and physicians believed that it was also included in the program. The other control drug showed no such decrease.

Third, a significant increase in pharmacist-initiated verification activity was noted after the Duval County program began. A highly publicized activity of this nature could be expected to have a positive effect in discouraging the presentation of forged prescriptions. The Duval County program was successful in heightening the pharmacists' awareness of the potential for prescription forgeries and subsequently, in increasing the number of prescriber contacts. However, it should be noted that under the guidelines of the voluntary program, the pharmacists were not required to make any notations when verification activity was performed. Therefore, the results may not reflect the true degree of the pharmacists' verification activities due to their failure to uniformly record them. In any future programs of like nature, pharmacists should be requested to record such notations directly on the prescription record in order to provide documentation and to allow for more efficient program evaluation.

Fourth, stock-size package prescribing activity exhibited a significant increase for both groups of drugs after initiation of the program. The discrepancy between methaqualone and amphetamine stock-size package prescribing is attributable to the package size of each product. Most of the frequently prescribed amphetamine drug products are available in bottles of 50 and 100, while no methaqualone products are available in bottles of less than 100. A larger increase in stock-size package prescribing of methaqualone would have increased the number of doses dispensed, an unwanted outcome. For future endeavors of this nature, the policy-makers should do one of two things; first, either enlist the manufacturers' aid to supply additional, more convenient package sizes, or second, delete the requirement if it is contrary to the primary goals of the program.

In their roles as decision-makers, the members of the Duval County Pharmacy Association, the Duval County Medical Society, and the Duval County Osteopathic Society implemented a policy designed to diminish the misuse of amphetamines and methaqualone in Jacksonville. Assessment of the implementation process parallels Chapter II's discussion of the process in general.

The first critical factor necessary for effective implementation is the establishment of an efficient communications system. Such a system delivers the right information to the right people at the right time. Information was disseminated to the general public via the printed and visual media. Pharmacists and physicians received their information from attendance at professional association meetings and professional journals. Unfortunately, there was a limited number of pharmacists who were made aware of the program via the printed media and thus, these individuals were initially confused as to the origin of the program [87].

A weakness in the communications system became evident during the course of this investigation. For example, a majority of the health professionals responding to the questionnaires erroneously believed that additional drugs were included in the program. Accurate, consistent and precise information transmittal mechanisms must be established, emphasized and reinforced in order to obtain effective policy implementation [62:43].

The second critical factor in effective implementation is adequacy of resources. Since each pharmacist or physician was responsible for making the decision regarding his participation in the program, each person had both the authority and apparently the adequate facilities to

execute that decision. The results indicate that there was a sufficient number of participants to achieve the goals of the program.

The third critical factor is the attitude of the implementers towards the Duval County program. The results indicate that the majority of the responding pharmacists and physicians favored the concept of the program. Attitudes are an important consideration for any future endeavors of this magnitude. Without sufficient support from the individuals responsible for implementing the policy, goal attainment is rarely possible.

The fourth critical factor is organizational structure. Each of the professional associations knew that without the support of the other two organizations, implementation would be more difficult. It was necessary that the interprofessional cooperation be maintained. Also, the corporate structure of chain pharmacies required that an effort be made to elicit the support of both the area supervisors and the working pharmacists in the chain pharmacies.

Another essential factor, not previously mentioned, is incentives. Edwards downplays this factor as a portion of attitude control [62:107], but this investigator believes that providing incentives is as critical an element as the other four factors. Incentives is the only factor over which policy-makers have direct control.

Incentives for pharmacists and physicians to participate in the program consisted of: first, an opportunity to help alleviate a portion of the problem of drug abuse; second, an opportunity to work in a different capacity with fellow health professionals; third, an opportunity to advance the standing of their respective professions; fourth, an opportunity to show that solutions to societal problems can be accomplished without governmental interference; and, fifth, and highly significant to the

pharmacists, the program was perceived as a mechanism for reducing the incidence of drug-related pharmacy crime. Each of these incentives was reinforced by the professional associations in their presentation of the program. The results indicate that these incentives were sufficient.

The overall results indicate that the Duval County program was generally successful in accomplishing its goals. The data show that changes remained in effect two years after the program began. This indicated that permanent behavioral changes had occurred in the prescribing and dispensing habits of physicians and pharmacists in Duval County. The survey results indicated that pharmacists and physicians believed that the number of forged prescriptions had been decreased and that several had been detected as a result of the program. Also, pharmacists believed that the number of burglaries and robberies had been decreased by reducing the "inventory of violence."

The results indicated that the communications system was the weak link in the implementation process for the Duval County program. Nonetheless, the program has provided important benefits. The interprofessional cooperation of the three associations resulting from the joint action has been maintained. The three associations are now jointly attempting to combat other aspects of drug misuse. A stolen prescription blank hotline is being maintained [88] and a new program modeled after the original Duval County program is currently in effect for two additional drugs that are being abused [89], pentazocine (Talwin®) and tripeleennamine (Pyribenzamine®), a combination known on the streets as "T's and blues," "blue velvet," or "blue heaven." The Duval County experiment has provided a model which others may wish to emulate.

### Policy Recommendations

Policy recommendations based upon this evaluative study are suggested for future programs of a voluntary nature. This discussion first examines general policy recommendations then it examines several factors critical to the implementation process that should be considered before a similar program is initiated.

Foremost is that the use of voluntary programs in health related areas should be expanded. The Duval County program showed that different groups of health professionals can work together in a united effort and succeed. Policy makers also should not discount the use of such programs in controlling specific areas of drug abuse.

Secondly, the results of the Duval County program signal a beacon of warning to the regulatory agencies (medical and pharmacy boards), the professional associations, and continuing education providers that there is an insufficient understanding of the law as it relates to medical and pharmacy practice. This inaccurate and imprecise knowledge has a potential for public harm that could potentially be corrected through educational activities. Repeated doses of simplified, understandable information to the practicing professional would provide a beginning step in augmenting their knowledge.

The program also provided a model for behavioral modification. A change in behavior was exhibited in both the pharmacists' dispensing habits and the physicians' prescribing habits. The actual change in behavior was for the public benefit in that it decreased the availability and accessibility of dangerous drugs. The process should be reinforced and expanded, which the Duval County professionals are currently undertaking. With the path towards success already paved for them, the mere



threat of instituting similar programs would alert the illicit market that one of their sources of drugs will disappear and they would react accordingly. The removal of frequently targeted drugs from inventory such as Dilaudid® or other "hard core" narcotics could be the next logical step in preventing drug related crimes against pharmacists.

Additionally, the Duval County program provides an excellent model of the value of public awareness of a problem. Policy-makers should not underestimate the value of public education to help solve a problem. The Duval County professionals and citizens are continuing to stay on top of the problems of community drug abuse and public awareness of this problem. Other communities should use this public support role model for similar voluntary programs.

Fifthly, policy-makers should not assume that global terms like "amphetamines" are clearly understood by implementers, participants, or the general public. The Duval County program indicated physicians and pharmacists misunderstood terms that the program designers assumed they would know. This is an important concept to remember when designing an information dissemination system.

Another recommendation is that voluntary programs should seek funding from outside sources. Even public funding via tax dollars should be considered whenever there is a logical reason to support this (e.g., a trade-off of tax money against robbery losses or loss of life). The lack of even this small funding can reduce implementation effectiveness and alter the final outcome, by reducing information availability or communications capability.

Finally, pharmaceutical manufacturers should heed the example set by the Duval County health professionals and provide more unit-of-use

stock packaging for dangerous drugs as a public service. The increase in packaging costs would be offset by good public will, by decreased "inventory of violence," and by warning potential prowlers that the rewards for their actions would be small indeed. National and state pharmacy associations should make this issue a high priority to stem the tide of rising pharmacy crime.

After program planning begins, policy makers must then begin their understanding of the roles which communications, implementer attitude, resource scarcity, and organizational structure play in the implementation process. The following recommendations are derived from the strengths and weaknesses discovered in the implementation assessment of the Duval County program. This discussion refers to Chapter II's discussion relative to the implementation process.

First, an assessment of the availability and adequacy of resources should be made. The primary resource is pertinent information of adequate detail and specificity. One of the mechanisms available that should be utilized to help assure access to this information is the continuing education process. The participating state and local professional associations should sponsor programs that are designed to accurately educate practitioners as to the specifics of new policies or programs. Where required by law, continuing education credits might serve as an incentive for practitioner participation. Another important resource is manpower. Sufficient manpower is necessary in order to perform the required tasks involved in implementing a novel program or policy. Also, sufficient financial resources are critical especially for the required postage and copying services that are required to disseminate the volume of information necessary for an efficient implementation process.

The second preliminary step is gathering the necessary political and attitudinal support for initiating a new policy or program. A positive attitude on the part of those who will be implementing a new program is imperative. The initial barrier to attitudinal support is making the potential participants recognize the seriousness of the problem to be tackled by the program. The support of the news media may be useful in accomplishing this recognition goal. Secondly, highlighting the incentives for each group's participation is important and is one method available for marshalling support. It is important that the relationship between incentives and attitudes be understood before the implementation stage is begun. Incentives may vary among persons of different cultural or ethnic and professional backgrounds.

Next, all potential participants, including those who are not members of the participating professional organizations, should be informed about the nature, purpose and effects of any such program before the information is disseminated to the general public. Establishment of a direct communication link to all potential participants is a necessary preliminary step for beginning the implementation process. Furthermore, information should continue to be provided to these individuals during the program's implementation to increase participation and compliance. The communications link should provide rapid, accurate, and understandable information through the utilization of various methods in order to make the communications as efficient and effective as possible. Possible forms of communications include the printed, oral, visual and aural media.

An understanding of organizational structure is also important for effective program implementation. The Duval County program was not a pharmacist-specific issue. Individual entrepreneurs and corporate

employee pharmacists each require different approaches to elicit their support. In the case of the large corporations, regional or district supervisors, as well as employee pharmacists, should be included early in the planning stages of the program to assure maximum participation and cooperation. Without an understanding of organizational structure of involved groups, implementation responsibility can be lost through organizational fragmentation.

Finally, it should be reemphasized that a detailed understanding of each of the four critical factors that impact on the implementation process and their interaction is necessary before beginning a novel program or policy. This discussion is meant as a guide when seeking to understand these four factors, it is not intended to be a cookbook on how to implement a program. Clear and concise communications of adequate detail and specificity with the program participants as often as possible can help eliminate some of the problems that were discovered in the Duval County program. Then as a first step after the planning process the local broadcast and printed mass media can be utilized to elicit the public support and understanding which is so crucial to such voluntary programs.

#### Areas for Future Research

Several avenues for future research have been identified as a result of this evaluative study. The first area involves several unanswered questions left by this evaluation:

- (1) What was the effect of the Duval County program on C-III and C-IV stimulants? These drugs could have been utilized as potential replacements for amphetamines.

- (2) What was the effect of the Duval County program on the surrounding counties' amphetamine and methaqualone prescription volume? Did the program solve a drug misuse problem or did it merely transfer the problem elsewhere?
- (3) What was the effect of the Duval County program on drug-related burglaries and robberies? Time and resource constraints prohibited the gathering of such data in this study.

The second avenue involves minor modifications in the research methodology and data collection instruments of this evaluation that would strengthen and enlarge the data analysis capabilities for future evaluations of similar programs:

- (1) Include the month that the program was initiated in the sample. This modification would provide more information on the implementation process and on the amount of time required to demonstrate changes in the prescribing and dispensing behaviors of the practitioners.
- (2) Include at least one additional evaluative control drug in the sedative-hypnotic class (i.e., same as methaqualone) in the sample. This modification would provide information on the spillover effects, either positive or negative, on this class of drugs.
- (3) Include more identical questions on the practitioners' questionnaires. This would provide for better comparison of the knowledge and attitudes of the pharmacists and physicians.
- (4) Delete or revise the section of the Physicians' Questionnaire pertaining to their drugs of choice for certain conditions.

The volume of information that was gathered by the present survey was insufficient for any meaningful analysis.

The third avenue would be to evaluate the effectiveness of alternative approaches to drug misuse control. For example, the effects of a voluntary program could be compared to the effects of a mandated policy. Specifically, the effect of the Florida amphetamine legislation on the volume of amphetamine prescriptions both in Duval County and in the state as a whole could be examined to identify marginal benefits, if any, gained in Duval County by the passage of this superceding legislative mandate which occurred in 1980. Also, the data could be utilized as a basis for the comparison of the results obtained from other counties to the results obtained from this evaluation of the Duval County program in order to determine which approach was the most successful. Another specific example would be a comparison of methaqualone overdose incidents which required treatment both prior to and after the recent Florida law went into effect. This law placed methaqualone into Schedule I thereby making it illegal to prescribe or to dispense the drug in Florida. The results from such a study would provide additional insight into the effectiveness of governmental actions in controlling specific areas of drug abuse.

### Conclusion

The efforts by the Duval County Pharmacy Association, the Duval County Medical Society, and the Duval County Osteopathic Society exhibited a high degree of peer review. This study has shown that voluntary peer review programs can have a significant impact upon societal problems when the professionals involve themselves in designing and carrying out that program.

APPENDIX I

PHARMACISTS' COMMENTS

Comments Made by Pharmacists  
During the Telephone Interview

- We no longer fill Schedule II prescriptions for strangers. (I)\*
- I am vehemently against the program, it limits professional judgment. (SC)
- Amphetamine users are going to Orange Park (Clay County) to get their prescriptions filled now. (I)
- The program is 99 plus percent effective, it decreases the pressure on the pharmacist. (LC)
- We definitely do not participate. This program causes a loss of professional discretion. (LC), (SC)
- The program has been a tremendous success. It has decreased breakage by 100 percent in this pharmacy. (I)
- We participated at first, but (a local large chain) didn't so we stopped our participation. (I)
- Keep the program voluntary. (SC), (I), (I)
- Program has failed, most pharmacists aren't participating. (I)
- A tremendous success in eliminating forgeries. (SC)
- We don't carry amphetamines or Quaaludes<sup>®</sup> at all anymore. (LC)
- The program has been very successful. We haven't had an Eskatrol<sup>®</sup> prescription in several years. (LC)
- Few pharmacists participated. The program failed. (LC)
- The program decreased our over-inventory of these drugs. (I)
- No recent robberies. (SC)

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\* (I)-Independent, (SC)-Small Chain, and (LC)-Large Chain are placed at the end of each comment to show the ownership category of the pharmacy.



- The program has decreased both thefts and forgeries. (I)
- Do not make this program a law. (I), (SC), (I)
- Do not make this program mandatory. (LC), (LC)
- A political move by the initiators to make a name for themselves. (I)
- I was hassled to participate. (I)
- Decreased the inventory of violence. (I)
- An exercise in futility, few pharmacies participated. (I)
- A way to decrease robberies. (LC)
- Keep program voluntary. (LC)
- A failure, independents don't participate. (LC)
- Go Gators! (I), (LC), (SC), (I), (I), (SC), (I), (LC)
- We participated at first, but the chains didn't so we changed. (I)
- Physicians are writing more Preludin<sup>®</sup> prescriptions instead of amphetamines. (I)
- Go Dawgs! (LC), (LC), (I), (I), (SC)

Comments of Pharmacists  
on the Pharmacists' Questionnaire

Question #9: Why did your pharmacy choose to participate or not to participate?

Non-Participating Pharmacies: Two pharmacies (7%)

- have confidence in my ability to set standard of ethics and morality on my own without outside interference.
- a C-II written legally should be filled at the time needed or otherwise it should not be written.

Participating Pharmacies: Twenty-one pharmacies (73%)

- sponsor of program, helped initiate the idea.
- to reduce as low as possible any amphetamine and methaqualone kept in stock and to discourage the use of these drugs.
- eliminate filling forged prescriptions.
- an ethical and practical solution to the problem.
- to cut down on illegal scripts.
- to reduce the amount of legal prescriptions in street use.
- excellent idea, curtails abuse.
- the thing to do to cut down on the forgeries for C-II's.
- too many break-ins looking for Preludin<sup>®</sup>, Biphetamines<sup>®</sup>, and Quaaludes<sup>®</sup>.
- I feel this is a good deterrent to fraudulent scripts.  
It also helps cut down on pharmacy robberies. It gives a pharmacist more control over to whom he dispenses the drugs.
- to cut down on script forgeries in Jacksonville.

- to cooperate in an effort to cut down illegal amphetamine and "Q" availability.
- a good safe-guard to discourage fraudulent prescriptions.
- to cut fake prescriptions.
- I started participating but stopped because all stores did not participate and this was unfair to those of us that did participate.
- to slow down the amount of forged scripts and the use of C-II drugs on the street.
- why not?
- we feel we have always exercised proper professional discretion.
- to reduce the slow-moving inventory items and for protection against holdups and break-ins.
- felt this program was needed.
- because of previous robberies and passing of forged scripts.

Did Not Respond: Six pharmacies (21%)

Question #10: Do you think the program has succeeded or failed? Why?:

Failed: Four pharmacies (14%)

- too few stores participated.
- a division among pharmacists' views on how this should be handled.
- many pharmacists did not follow the rules strictly.
- erratic participation.

Succeeded: Nineteen pharmacies (65%)

- all the pharmacists working together, public pressure and physician education.

- usage of drugs involved decreased greatly.
- doctors seem to be a little more careful in what they prescribe.
- cooperation of physicians, pharmacists and customers.
- helps the pharmacist limit inventory and lessen the chances of crimes against him.
- decrease amphetamines and "ludes" by 75%.
- it has reduced the number of strangers that show up with amphetamine prescriptions.
- very little break-ins.
- this program has made it a lot easier to verify prescriptions.
- we are now dispensing one third the amount of "Q's" and zero amphetamine scripts.
- it served the purpose.
- but only because it essentially paralleled federal regulatory changes.
- I carry less C-II drugs. The program put pressure on the Duval County Medical Society to put pressure on the few physicians that were abusing the C-II's.

Did Not Respond: Six pharmacies (21%)

#### General Comments:

- keep program voluntary.
- the program has helped the public image of pharmacy, but it has really made most of us a two-faced liar.
- I am 100% in favor of this program. It is something we have needed for a long time.

- I am in favor of federal triplicate narcotic forms.
- Law enforcement agents should concentrate at the street level not the drug store. We are pharmacists, and the police treat us as if we are the dealers and pushers of C-II drugs.

APPENDIX II

PHARMACISTS' QUESTIONNAIRE

## Pharmacist Survey

Please check the appropriate response(s).

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1. New Prescriptions as a % of Total Prescriptions

- ☐ under 25%
- ☐ 25% to 50%
- ☐ 51% to 75%
- ☐ over 75%

2. Are you aware of the new Florida law (effective July 1980) concerning the prescribing and dispensing of amphetamines?

- ☐ yes
- ☐ no

If no, skip to question 5.

3. To your knowledge which of these drugs are affected by the new law? (check all that apply):

- ☐ applies to amphetamines
- ☐ applies to phenmetrazine (Preludin)
- ☐ applies to methylphenidate (Ritalin)
- ☐ applies to benzphetamine (Didrex)
- ☐ applies to phentermine (Ionamin, Fastin)
- ☐ applies to phendimetrazine (Plegine)
- ☐ applies to all sympathomimetic amines

4. To your knowledge which of the following uses are now indicated for amphetamines in Florida? (check all that are indicated):

- ☐ narcolepsy
- ☐ hyperkinesis in children
- ☐ anorexia
- ☐ depression refractory to other therapies
- ☐ obesity
- ☐ clinical investigations
- ☐ weight loss programs under a physicians care
- ☐ clinical investigations submitted to and approved by the Medical Board
- ☐ metabolic stimulant

5. Are you aware of the Duval County Pharmacy Association's voluntary program (initiated in late 1977) concerning the dispensing of amphetamines and some other Schedule-II drugs?

- ☐ yes
- ☐ no

If no, skip to question 25.

6. To your knowledge which of these are features of the Duval County program? (check all that apply):

- ☐ ( ) applies to amphetamines
- ☐ ( ) applies to methaqualone (Quaalude, Sopor)
- ☐ ( ) applies to Dilaudid
- ☐ ( ) applies to Percodan
- ☐ ( ) applies to phenmetrazine (Preludin)
- ☐ ( ) applies to all C-II prescriptions
- ☐ ( ) requests a 24-hour moratorium after receipt of a prescription before dispensing it
- ☐ ( ) requests dispensing in "unit-of-use" packaging only
- ☐ ( ) applies only to prescriptions written by Jacksonville physicians
- ☐ ( ) requests a 48-hour moratorium after receipt of a prescription before dispensing it
- ☐ ( ) applies only to customers who are not regular customers of that particular establishment

7. Does your pharmacy participate in this program?

- ☐ ( ) yes, all the time
- ☐ ( ) yes, but only for non-regular customers
- ☐ ( ) no, but we have participated in the past
- ☐ ( ) no, never

8. Specify the period during which your pharmacy has participated in this program?

From \_\_\_\_\_ 19\_\_\_\_; To \_\_\_\_\_ 19\_\_\_\_  
                     (month)                                    (month)

9. Why did your pharmacy choose to participate or not to participate?

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10. Do you think that the program has succeeded or failed? Why?

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Pharmacist Attitude Survey

Indicate the extent that you agree with the following statements by checking the appropriate column.

		Strongly Agree			Strongly Disagree	
		1	2	3	4	5
11.	The Jacksonville program has been succeeding in curbing amphetamine misuse.	( )	( )	( )	( )	( )
12.	In general, local doctors have accepted the program.	( )	( )	( )	( )	( )
13.	In general, most local pharmacists were coerced into participating in the program.	( )	( )	( )	( )	( )
14.	The delay in dispensing has caused numerous customers to go elsewhere.	( )	( )	( )	( )	( )
15.	Generally, most customers have accepted this project as a necessary way to control drug abuse.	( )	( )	( )	( )	( )
16.	A significant number of patients are going across county lines to get their amphetamine prescriptions filled.	( )	( )	( )	( )	( )
17.	Pressure from fellow pharmacists was the reason many pharmacies agreed to participate in the program.	( )	( )	( )	( )	( )
18.	In general, doctors are continuing to over prescribe these drugs.	( )	( )	( )	( )	( )

## Pharmacist Attitude Survey (cont...)

		Strongly Agree				Strongly Disagree	
		1	2	3	4	5	
19.	There has been a significant increase in physician dispensing of amphetamines as a result of this program.	( )	( )	( )	( )	( )	
20.	Most pharmacists that participate do so only for their non-regular customers.	( )	( )	( )	( )	( )	
21.	Public pressure was the reason many pharmacies agreed to participate in the program.	( )	( )	( )	( )	( )	
22.	The Duval County experiment should be expanded to a state-wide level.	( )	( )	( )	( )	( )	
23.	The Duval County program should be made mandatory.	( )	( )	( )	( )	( )	
24.	The Duval County Pharmacy Association applied pressure to get most of the pharmacists to participate in the program.	( )	( )	( )	( )	( )	
25.	The anti-obesity indication should <u>NOT</u> be a FDA approved use of amphetamine drugs.	( )	( )	( )	( )	( )	
26.	The new state law banning the use of amphetamines for weight control will help curb their misuse.	( )	( )	( )	( )	( )	

Pharmacist Attitude Survey (cont...)

	Strongly Agree			Strongly Disagree	
	1	2	3	4	5
27. The source of most illicit "street" drugs is the resale of drugs obtained through a prescription.	( )	( )	( )	( )	( )
28. State and federal attempts to curb drug abuse have been very successful in decreasing the problem.	( )	( )	( )	( )	( )

COMMENTS:

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Pharmacist Classification Survey

Please check the appropriate response(s).

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## 29. Type of ownership

- ☐ Independent (only a single pharmacy is owned)
- ☐ Small Chain (2 to 10 pharmacies which have a common ownership)
- ☐ Large Chain (more than 10 pharmacies which have a common ownership)

## 30. Years in practice

- ☐ 0 to 5
- ☐ 6 to 15
- ☐ over 15

## 31. Member of the American Pharmaceutical Association (APhA)?

- ☐ yes
- ☐ no

## 32. Member of the Florida Pharmacy Association (FPA)?

- ☐ yes
- ☐ no

## 33. Member of the Duval County Pharmacy Association?

- ☐ yes
- ☐ no

APPENDIX III

COVER LETTER TO PHYSICIAN QUESTIONNAIRE

UNIVERSITY OF FLORIDA  
COLLEGE OF PHARMACY (Box J-4)

J. HILLIS MILLER HEALTH CENTER

GAINESVILLE  
32610

August 3, 1981

Dear Physician:

We are soliciting your input on a question of national importance.

The Drug Enforcement Administration has shown interest in a Duval County project jointly sponsored by the Duval County Medical Society and the Duval County Pharmacy Association. This project, initiated in 1978, was a voluntary program that bans the dispensing of certain C-II controlled substances for 48 hours after receipt of the prescription by the pharmacist. The D.E.A.'s interest is in why this project succeeded or failed.

You can assist in this evaluation by filling out the enclosed questionnaire. Please take the time to read and answer the questions. Mark your answer(s) as indicated on the survey. There is ample space on the pages for comments and suggestions. Please feel free to comment. We enthusiastically welcome your input.

This is your opportunity to advise the D.E.A. of your feelings on controlled substance regulation. Please answer and mail back the survey in the stamped and addressed envelope provided no later than August 25, 1981.

Thank you for your time and trouble.

Sincerely,

Barry A. Bleidt, C.Ph.  
Ph.D. Candidate in  
Pharmacy Health Care Administration

William C. McCormick, Ph.D.  
Associate Professor and Chairman  
Pharmacy Health Care Administration

Enclosure

APPENDIX IV

PHYSICIANS' MAIL QUESTIONNAIRE

## PHYSICIAN MAIL QUESTIONNAIRE

Please check the appropriate response(s).

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1. Are you aware of the new Florida law (effective July 1980) concerning the prescribing and dispensing of amphetamines?  
☐ yes  
☐ no  
If no, skip to question 4.
2. To your knowledge which of these drugs are affected by the new law? (check all that apply):  
☐ applies to amphetamines  
☐ applies to phenmetrazine (Preludin)  
☐ applies to methylphenidate (Ritalin)  
☐ applies to benzphetamine (Didrex)  
☐ applies to phentermine (Ionamin, Fastin, Pre-Sate)  
☐ applies to phendimetrazine (Plegine)  
☐ applies to all sympathomimetic amines
3. To your knowledge which of the following indications or uses are now proper for amphetamines in Florida? (check all that are proper):  
☐ narcolepsy  
☐ hyperkinesis in children  
☐ anorexia  
☐ depression refractory to other therapies  
☐ obesity  
☐ clinical investigations  
☐ weight loss programs under a physician's care  
☐ clinical investigations submitted and approved by the medical board  
☐ metabolic stimulant
4. Are you aware of the Duval County Pharmacy Association's voluntary program (initiated in 1978) that bans the dispensing of amphetamines for 48 hours after receipt of the prescription?  
☐ yes  
☐ no  
If no, skip to question 17.



5. To your knowledge which of these are features of the Duval County program? (check all that apply):

- ☐ applies to amphetamines
- ☐ applies to methaqualone (Quaalude, Sopor)
- ☐ applies to Dilaudid
- ☐ applies to Percodan
- ☐ applies to phenmetrazine (Preludin)
- ☐ applies to all Schedule-II (C-II) drugs
- ☐ applies only to prescriptions written by Jacksonville physicians
- ☐ requests dispensing in "unit-of-use" packaging
- ☐ applies only to customers who are not regular customers of that particular establishment.

6. Are you aware of any pharmacies that are participating in this moratorium?

- ☐ yes
- ☐ no

7. a) Have you been contacted about the validity of an amphetamine prescription by a pharmacist?

- ☐ yes
- ☐ no
- ☐ does not apply, I don't prescribe amphetamines

- b) you think that it was because of the 48-hour "cooling off" period?

- ☐ yes
- ☐ no

- c) Has there ever been a forged prescription detected as a result of these contacts?

- ☐ yes
- ☐ no

- d) If yes, how many times?

- \_\_\_\_\_ 1
- \_\_\_\_\_ 2 to 5
- \_\_\_\_\_ over 5

8. Because of the publicity and/or the program, has there been a change in your prescribing of amphetamines?

- ☐ yes, I have decreased my prescribing
- ☐ yes, I have increased my prescribing
- ☐ no

9. Are you aware of any of your patients having a difficult time having their prescriptions for amphetamines filled?

- ☐ yes, to a large extent  
☐ yes, but only to a small degree  
☐ no  
☐ does not apply, I don't prescribe amphetamines

10. Do you think there has been an increase in the number of physicians who dispense amphetamines as a result of the moratorium?

- ☐ yes  
☐ no

Please indicate the extent that you agree with the following statements by checking the appropriate column.

	Strongly Agree				Strongly Disagree	
	1	2	3	4	5	
11. The Duval County voluntary moratorium has been effective in decreasing amphetamine misuse or abuse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. The Duval County voluntary moratorium is in general a good concept.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. The voluntary moratorium should be expanded to a state-wide level.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. The voluntary moratorium should be made mandatory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. The anti-obesity indication should <u>NOT</u> be a FDA approved use of amphetamine drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. The new state law banning the use of amphetamines for weight control will help curb their misuse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	Strongly Agree				Strongly Disagree
	1	2	3	4	5
17. The source of most illicit "street" drugs is the resale of drugs obtained through a prescription.	( )	( )	( )	( )	( )
18. State and federal attempts to curb drug abuse have been very successful in decreasing the problem.	( )	( )	( )	( )	( )

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

19. Please indicate what drugs you prescribed for the following conditions in 1977 (the year preceding the Duval County program). Indicate both your first and second choice if you prescribed more than one drug for the condition. If you did not prescribe for the condition, place a check mark ( ) in the third column.

Type of Condition	First Choice	Second Choice	Did not prescribe for this condition
C-II Anorexiant			
Non-Class II Anorexiant			
Hyperkinesia in children			
Narcolepsy			
Weight Control			

20. Please indicate what drugs you prescribed for the following conditions in 1979 (the year after the Duval County program began). Indicate both your first and second choice if you prescribed more than one drug for the condition. If you did not prescribe for the condition, place a check mark ( ) in the third column.

Type of Condition	First Choice	Second Choice	Did not prescribe for this condition
C-II Anorexiant			
Non-Class II Anorexiant			
Hyperkinesia in children			
Narcolepsy			
Weight Control			

21. Please indicate what drugs you prescribe NOW for the following conditions (after the new state law on amphetamine prescribing was enacted). Indicate both your first and second choice if you prescribe more than one drug for the condition. If you do not prescribe for the condition, place a check mark ( ) in the third column.

Type of Condition	First Choice	Second Choice	Did not prescribe for this condition
C-II Anorexiant			
Non-Class II Anorexiant			
Hyperkinesia in children			
Narcolepsy			
Weight Control			

Physician Classification Data

Please check the appropriate response(s).

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22. Sex

☐ Male  
☐ Female

23. Age

☐ less than 35  
☐ 35 to 50  
☐ 51 to 65  
☐ over 65

24. Member of AMA

☐ yes  
☐ no

25. Member of Duval County Medical Society

☐ yes  
☐ no

26. Specialty

☐ Family Practice  
☐ General Practice  
☐ Internal Medicine  
☐ Diet/Weight Control  
☐ Dermatology  
☐ Ear, Nose, Throat  
☐ Obstetrics/Gynecology  
☐ Ophthalmology  
☐ Pediatrics  
☐ Psychiatry  
☐ Other \_\_\_\_\_

(please specify)

APPENDIX V

DRUG PRODUCT CODING SYSTEM

## Drug Product Coding System

Code	Drug Product
Methylphenidate	
11	Ritalin® 5 mg Tablets
12	Ritalin® 10 mg Tablets
13	Ritalin® 20 mg Tablets
Phenmetrazine	
21	Preludin® 25 mg Tablets
22	Preludin® 50 mg Tablets
23	Preludin® 75 mg Endurets®
Methaqualone	
31	Quaalude® 150 mg Tablets (Mequin-150®)
32	Quaalude® 300 mg Tablets (Mequin-300®)
33	Sopor® 150 mg Tablets
34	Sopor® 300 mg Tablets
35	Parest® 200 mg Capsules
36	Parest® 400 mg Capsules
Amphetamine Liquids	
41	Dexamyl® Elixir
42	Dexedrine® Elixir
Amphetamine Combination Products	
51	Dexamyl™ Tablets
52	Dexamyl™ #1 Spansules™
53	Dexamyl™ #2 Spansules™

## Drug Product Coding System (Continued...)

Code	Drug Product
54	Biphetamine-7.5 <sup>®</sup> Capsules
55	Biphetamine-12.5 <sup>®</sup> Capsules
56	Biphetamine-20 <sup>®</sup> Capsules
57	Eskatrol <sup>®</sup> Spansules <sup>®</sup>
	Methamphetamine
61	Desoxyn <sup>®</sup> 2.5 mg Tablets
62	Desoxyn <sup>®</sup> 5 mg Tablets
63	Desoxyn <sup>®</sup> 10 mg Tablets
64	Desoxyn <sup>®</sup> 15 mg Tablets
65	Syndrox <sup>®</sup> Tablets
	d-Amphetamine
71	Dexedrine <sup>®</sup> 5 mg Spansules <sup>®</sup>
72	Dexedrine <sup>®</sup> 10 mg Spansules <sup>®</sup>
73	Dexedrine <sup>®</sup> 15 mg Spansules <sup>®</sup>
74	Dexedrine <sup>®</sup> 5 mg Tablets
75	Dexedrine <sup>®</sup> 15 mg Tablets
	d-l Amphetamine
81	Benzedrine <sup>®</sup> 5 mg Tablets
82	Benzedrine <sup>®</sup> 10 mg Tablets
33	Benzedrine <sup>®</sup> 15 mg Capsules
34	Obetrol <sup>®</sup> Tablets
35	Obetrol-20 <sup>®</sup> Tablets
86	Obedrin <sup>®</sup> Tablets
37	Obedrin-LA <sup>®</sup> Tablets



## Drug Product Coding System (Continued...)

Code	Drug Product
Miscellaneous	
91	d-Amphetamine Compound (Old Daprisal <sup>®</sup> formula)
92	Amphetamine/Dramamine <sup>®</sup> Compound

APPENDIX VI

DATA COLLECTION CODE SHEET

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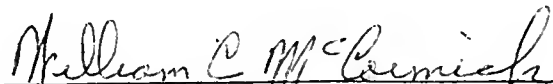
## BIOGRAPHICAL SKETCH

Barry Anthony Bleidt was born March 29, 1951 in South Charleston, West Virginia. In May 1969 he matriculated from George Washington High School after serving his school as the student director of the school band and director of the pep band, and being selected as a member of the All County Chorus. He attended the University of Kentucky from August 1969 to December 1974. He was a fourth generation Kentucky graduate when he graduated with distinction from the College of Pharmacy there.

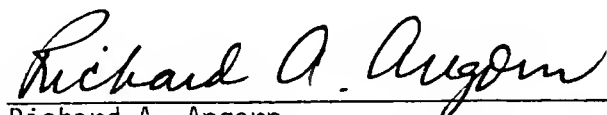
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He was married to the former Deborah Sophia Catania on August 17, 1979 in Hollywood, Florida.

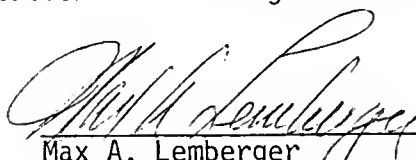
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William C. McCormick, Chairman  
Associate Professor of Pharmacy


I certify that I have read this study and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Doctor of Philosophy.

  
Richard A. Angorn  
Associate Professor of Pharmacy

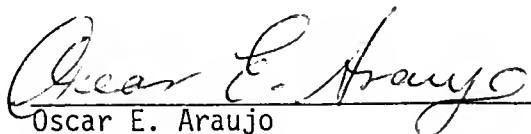
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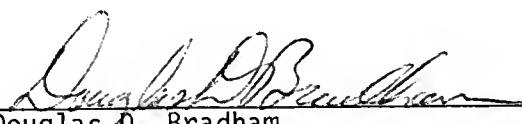
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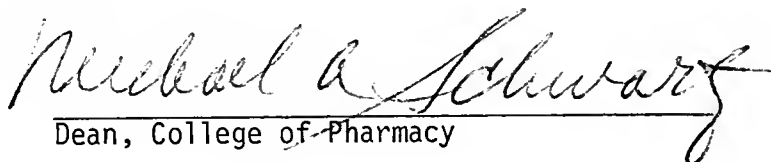
  
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